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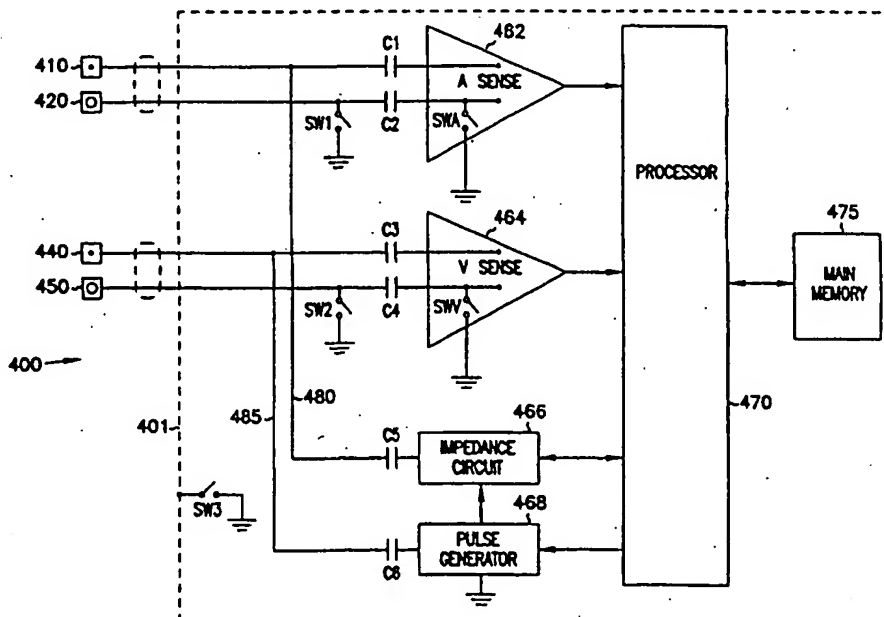
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(54) Title: IMPLANTABLE CARDIAC STIMULATOR WITH ELECTRODE-TISSUE INTERFACE CHARACTERIZATION

(57) Abstract

A cardiac stimulator capable of measuring pacing impedance includes a tank capacitor for delivering charge to the heart via device leads, a shunt resistor, and high-impedance buffers for measuring pacing current through the shunt resistor. Soon after the leading edge of the stimulation pulse, the voltage across the shunt resistor, as sampled by a high-impedance buffer, indicates lead and cardiac tissue resistance. Just prior to opening the pacing switch to terminate the stimulation pulse, the voltage across the shunt resistor is sampled by a high-impedance buffer and held once against to allow the capacitance of the lead/heart tissue to be calculated. In alternative embodiments, a high-impedance buffer measures

the voltage between the tank capacitor and ground immediately following the stimulation pulse to allow estimation of the lead/heart tissue capacitance. In one alternative embodiment, a look-up table is created in main memory and searched to find the closest lead/heart tissue capacitance estimate to any arbitrary degree of accuracy. In another alternative embodiment, the lead/heart tissue capacitance is estimated by successive approximation to any arbitrary degree of accuracy. When the lead/heart tissue capacitance and lead resistance have been determined, a plurality of parameters of importance for analyzing and optimizing a cardiac stimulation system may be calculated, such as the instantaneous current, the average current, the charge, and the energy delivered to the cardiac tissue.



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IMPLANTABLE CARDIAC STIMULATOR WITH ELECTRODE-TISSUE INTERFACE CHARACTERIZATION

BACKGROUND OF THE INVENTION

5 Field of the Invention

The present invention relates generally to implantable cardiac pacing systems and particularly to an improved technique for electrode-tissue interface characterization. More particularly, the present invention relates to an apparatus and method for measuring the resistive and capacitive
10 components of the impedance of pacemaker or defibrillator leads.

Background of the Invention

In the normal human heart, illustrated in Figure 1, the sinus (or sinoatrial (SA)) node generally located near the junction of the superior vena cava and the right atrium constitutes the primary natural pacemaker by which
15 rhythmic electrical excitation is developed. The cardiac impulse arising from the sinus node is transmitted to the two atrial chambers (or atria) at the right and left sides of the heart. In response to excitation from the SA node, the atria contract, pumping blood from those chambers into the respective ventricular chambers (or ventricles). The impulse is transmitted to the
20 ventricles through the atrioventricular (AV) node, and via a conduction system comprising the bundle of His, or common bundle, the right and left bundle branches, and the Purkinje fibers. The transmitted impulse causes the ventricles to contract, the right ventricle pumping unoxygenated blood through the pulmonary artery to the lungs, and the left ventricle pumping oxygenated
25 (arterial) blood through the aorta and the lesser arteries to the body. The right atrium receives the unoxygenated (venous) blood. The blood oxygenated by the lungs is carried via the pulmonary veins to the left atrium.

This action is repeated in a rhythmic cardiac cycle in which the atrial and ventricular chambers alternately contract and pump, then relax and fill.
30 Four one-way valves, between the atrial and ventricular chambers in the right and left sides of the heart (the tricuspid valve and the mitral valve, respectively), and at the exits of the right and left ventricles (the pulmonic and

aortic valves, respectively, not shown) prevent backflow of the blood as it moves through the heart and the circulatory system.

The sinus node is spontaneously rhythmic, and the cardiac rhythm it generates is termed normal sinus rhythm ("NSR") or simply sinus rhythm.

5 This capacity to produce spontaneous cardiac impulses is called rhythmicity; or automaticity. Some other cardiac tissues possess rhythmicity and hence constitute secondary natural pacemakers, but the sinus node is the primary natural pacemaker because it spontaneously generates electrical pulses at a faster rate. The secondary pacemakers tend to be inhibited by the more rapid
10 rate at which impulses are generated by the sinus node.

Disruption of the natural pacemaking and propagation system as a result of aging or disease is commonly treated by artificial cardiac pacing, by which rhythmic electrical discharges are applied to the heart at a desired rate from an artificial pacemaker. An artificial pacemaker (or "pacer") is a medical
15 device which delivers electrical pulses to an electrode that is implanted adjacent to or in the patient's heart in order to stimulate the heart so that it will contract and beat at a desired rate. If the body's natural pacemaker performs correctly, blood is oxygenated in the lungs and efficiently pumped by the heart to the body's oxygen-demanding tissues. However, when the body's natural
20 pacemaker malfunctions, an implantable pacemaker often is required to properly stimulate the heart. An in-depth explanation of certain cardiac physiology and pacemaker theory of operation is provided in U.S. Patent No. 4,830,006.

Pacers today are typically designed to operate using one of three
25 different response methodologies, namely, asynchronous (fixed rate), inhibited (stimulus generated in the absence of a specified cardiac activity), or triggered (stimulus delivered in response to a specified hemodynamic parameter). Broadly speaking, the inhibited and triggered pacemakers may be grouped as "demand" type pacemakers, in which a pacing pulse is only
30 generated when demanded by the heart. To determine what pacing rate is required by the pacemaker, demand pacemakers may sense various conditions such as heart rate, physical exertion, temperature, and the like.

Moreover, pacemaker implementations range from the simple fixed rate, single chamber device that provides pacing with no sensing function, to highly complex models that provide fully automatic dual chamber pacing and sensing functions. The latter type of pacemaker is the latest in a progression
5 toward physiologic pacing, that is, the mode of artificial pacing that most closely simulates natural pacing.

Referring now to Figure 2, a conventional implantable medical device 200 is shown implanted and coupled to a patient's heart 250 by leads 205 and 210. The implantable medical device 200 may include a pacemaker or
10 defibrillator or any medical device that performs pacing or defibrillating functions. The implanted medical device 200 (or simply "pacer") also includes a housing or "can" 215 which houses a battery and pacing or defibrillating circuitry (not shown). In the dual chamber pacing arrangement shown, leads 205 and 210 are positioned in the right ventricle and right atrium, respectively.
15 Each lead 205 and 210 includes at least one stimulating electrode for delivery of electrical impulses to excitable myocardial tissue in the appropriate chamber(s) in the right side of the patient's heart. As shown in Figure 2, each lead 205 and 210 includes two electrodes. More specifically, lead 210 includes ring electrode 230 and tip electrode 235, and lead 205 includes ring
20 electrode 220 and tip electrode 225. Two, three, and four terminal devices all have been suggested as possible electrode configurations.

A lead configuration with two electrodes is known as a "bipolar lead." Such a configuration typically consists of a pair of wires arranged coaxially and individually insulated. Each of the wires may consist of multiple wire
25 strands wrapped together for redundancy. A circuit consisting of the pacemaker 200 and the heart muscle can be formed by connecting the lead electrodes to different portions of the heart muscle. In a bipolar configuration, electric current impulses generally flow from the ring electrode through the heart muscle to the tip electrode, although current may travel from the tip
30 electrode to the ring electrode in alternative configurations. A lead with one electrode is known as a "unipolar lead." In a unipolar configuration, the

pacemaker can 215 functions as an electrode. Current flows from the unipolar lead through the heart tissue, returning to the pacer via the can 215.

In general, a pacing pulse current is formed by the flow of charge carriers in the circuit formed by the lead and tissue. Because the electrode is typically composed of a solid conductive material, while the myocardial tissue consists of liquid electrolyte, the electrode forms an electrode/electrolyte interface through which the charge carriers pass. Accordingly, electron conductivity accounts for charge transfer in the lead circuit and in the solid phase of the electrode interface, while ion conductivity is the primary mechanism responsible for charge flow through the electrolyte interface and tissues.

At the interface layer, pacing pulse charge flows from the solid phase of the electrode interface to the electrolyte phase until the electrochemical potential of the electrode interface balances the electrochemical potential of the electrolyte interface. During such a process, an electric charge layer, known as the Helmholtz layer, forms around the surface of the electrode. While the exact nature of the Helmholtz layer is very complex, it can be generally modeled as an electric circuit using voltage sources, diodes, and/or devices that contribute impedance (which is the ability to impede electric current) to the lead-tissue circuit. Electrical impedance may be generally characterized by the combination of a resistive component, such as a resistor, with a reactive component, such as a capacitor or inductor. One Helmholtz layer model includes a polarization potential (known as the "Helmholtz voltage") in series with the parallel combination of a resistor (known as the "Warburg resistor") and a capacitor (known as the "Helmholtz capacitor"). A second Helmholtz layer model has been suggested which consists of an impedance circuit shunted by two zener diodes. The second configuration accounts for the electrical behavior of heart tissue when the interface voltage exceeds several hundred millivolts. A simple yet accurate model of the Helmholtz layer consists of the Warburg resistance in series with a voltage-dependent Helmholtz capacitance, eliminating the need to model the polarization potential.

Figure 3A illustrates a model of a conventional cardiac stimulator circuit consisting of a pacer 200, heart tissue 250, and bipolar pacer lead 205 terminated by tip electrode 225 and ring electrode 220. Ring electrode 220 and tip electrode 225 couple the pacer 200 to different portions of the heart tissue 250. Alternatively, a model as in Figure 3B using a unipolar lead 305 would include a single electrode 320 coupled to the heart tissue 250 with the pacer can 215 coupled to the chest tissue, labeled as ground. In the unipolar configuration of Figure 3B, the pacer 200 sends electric current from the pacer can 215 to a single electrode 320 through the chest and heart tissue 250. Accordingly, the impedance introduced by the combination of chest tissue (Figure 3B only), bipolar lead 205 or unipolar lead 305, and heart tissue 250 may be collectively modeled by resistor R3 (the Warburg resistor) in series with capacitor C3 (the Helmholtz capacitor).

Such models as shown in Figure 3A and 3B are important for delivering "pacing impedance" estimates, which help to indicate the condition of the pacer leads as well as to estimate electric charge, current, and energy delivered to the heart tissue. Particularly, deviations that occur over time in the pacing impedance serve to indicate the conditions related to the pacing or defibrillation lead system. Such conditions include electrode micro-dislocation, lead impedance changes, evaluation of electrode suitability for detecting evoked potentials, and methods for detecting changes in the excitable tissue as a function of catecholamine concentration, metabolic changes, and ischemia. In addition, the charge, current, energy, and impedance measurements allow physicians to estimate the longevity of the implanted device. Accordingly, pacing impedance estimates aid physicians in maintaining and optimizing pacemaker operation throughout the life of the device.

Although a purely resistive lead impedance estimate may provide a means for a rough estimate of pacer and battery condition, such an estimate may deviate significantly from the true impedance in some situations, since the physical and electrochemical properties that lead to the Helmholtz layer change with variations in the electric field intensity which develops at the electrode-

electrolyte interface. For example, corrosion, electrocatalysis of glucose and amino acids, and hydrogen ion potentiodynamics drastically alter the modeled capacitance, resistance, and polarization of the interface, as do electrode current density and electric field strength. Further, the Helmholtz capacitance varies according to a parameter known as the "microsurface area" of the electrode. The microsurface area of the electrode is the total surface area of the electrode material, including microscopic details such as porosity and other microscopic details. Typically, the Helmholtz capacitance equals about 100 microfarads (μF) per square centimeter of microsurface area. In addition, the resistance, capacitance, and polarization voltage of the Helmholtz layer can vary according to the duration and amplitude of the pacing pulse, although these properties are approximately constant for pulse widths of less than 0.5 milliseconds (ms) and pulse amplitudes of less than 0.5 volts (V).

Methods for measuring the resistive component of pacing impedance have been available for some time as part of the information that implantable pacemakers and defibrillators can collect and telemeter. However, such estimates have neglected the reactive impedance component, as modeled by the Helmholtz capacitance, resulting in an incomplete characterization of the pacing impedance. Such omissions produce undesirable impedance estimation errors which may propagate into subsequent calculations of charge, current, and energy delivered to the heart tissue as well as other conditions closely related to the pacing impedance. Impedance-based methods for monitoring the leads and electrodes of implantable cardiac stimulators have been described in a number of patents, including U.S. Patent No. 4,899,750, U.S. Patent No. 5,201,865, and U.S. Patent No. 5,534,018 which disclose devices for estimating the resistive lead impedance component.

While measurement of the Helmholtz capacitance has been suggested using alternating current (AC) circuits, such circuits are not practical for use with cardiac stimulation devices, which typically use direct current (DC) pulses for cardiac stimulation. Accordingly, devices using AC methods must operate exclusively of normal pacemaker/defibrillator operation. Therefore, no

practical device or method for estimating both the resistive and reactive components of pacer lead impedance has been devised within a cardiac stimulator, and present-day cardiac stimulators must tolerate the inaccuracies introduced by purely resistive impedance estimates, as described above.

5 For the foregoing reasons, a practical apparatus for measuring both the resistive and capacitive components of the lead impedance, including the Helmholtz layer, would greatly improve the implementation of implanted stimulation devices. Such an apparatus, if devised, should be adapted to measure lead impedance during normal operation of the implanted device
10 without affecting the functionality of the pacing or defibrillating circuit. The resulting device would significantly improve the accuracy of cardiac impedance estimates, resulting in superior optimization and maintenance of implanted devices. Unfortunately, to date, no such device is known that provides these features.

15

SUMMARY OF THE INVENTION

Accordingly, there is provided herein a cardiac stimulator including a pulse generator for delivering current to the heart tissue, an impedance measurement circuit coupled to the pulse generator, and a processor for
20 performing control and calculation functions. Upon receiving control signals from the processor, the pulse generator transmits electric current (known as a pacing pulse) from a charged capacitor into the heart tissue. At the same time, the processor asserts control pulses to the impedance circuit, causing the impedance circuit to sample voltages from the pulse generator. The impedance
25 circuit records the voltage measurements through sample-and-hold units, transmitting the voltages as signals to the processor. Using these voltage measurements, the processor calculates the impedance of the lead/tissue circuit.

The pulse generator includes a tank capacitor for delivering charge to the
30 heart via device leads and a pacing voltage source for charging the tank capacitor through an electronically-controlled charge switch. Just prior to the time that the pacing pulse is to be delivered to the heart tissue, the charge

switch is opened. A pacing switch is then closed to allow charge from the tank capacitor to flow through a DC-blocking capacitor into the lead and subsequently the heart. Opposing the flow of this current are the resistance of the pacing switch, the resistive components of the lead and load impedance (i.e., the lead resistance and ionic resistance), the Helmholtz capacitance, and a
5 current-measurement-shunt resistor.

Soon after the leading edge of the pacing pulse, or at time $t = (0^+)$, the voltage across the current-measurement-shunt resistor is sampled through a high-impedance buffer and held. Since the DC-blocking and Helmholtz
10 capacitances have not charged appreciably at $t = (0^+)$, they behave as short-circuits. The pacing circuit is therefore purely resistive, and the lead and ionic resistance may be calculated by the method of circuit analysis.

Just prior to opening the pacing switch to terminate the pacing pulse, or at time $t = (T_{PW}^-)$, the voltage across the current-measurement-shunt resistor is
15 sampled by a high-impedance buffer and held once again to allow the Helmholtz capacitance to be calculated. After the pacing pulse is delivered and before the tank capacitor is recharged, the end voltage of the tank capacitor is sampled through a high-impedance buffer and held. Concurrently with the sampling of the tank capacitor end voltage, the DC-blocking capacitor discharges into the
20 human body by an active discharge switch and a passive-discharge resistor. In a preferred embodiment, the resistive and capacitive components of the lead impedance may be calculated explicitly using the shunt resistor voltage samples from the high-impedance buffers.

In other embodiments, the apparatus estimates the Helmholtz
25 capacitance without knowledge of the voltage across the current-measurement-shunt resistor just prior to the end of the pulse. The voltage across the tank capacitor after the pulse ends, i.e. at $t = (T_{PW}^+)$, may be expressed using a formula based on pacing voltage, tank capacitance, DC-blocking capacitance, Helmholtz capacitance, current-measurement-shunt resistance, pacing switch
30 resistance, lead/tissue resistance, and pulse width, all of which are known values except the Helmholtz capacitance and lead/tissue resistance. The tank voltage formula consists of an exponential term multiplied by a constant term

and added to an additive term. All three terms include the Helmholtz capacitance as a variable. If the tank capacitor voltage is measured following the pulse and the lead/tissue resistance is calculated using circuit analysis as above, then the formula reduces to an equation involving only one unknown variable, the Helmholtz capacitance.

In an alternative embodiment, a look-up table is created in main memory by using the calculated Warburg resistance combined with known values of the pacing voltage, tank capacitance, DC-blocking capacitance, current-measurement-shunt resistance, pacing switch resistance, and pulse width in the formula along with a series of empirical estimates for the value of the Helmholtz capacitance. The formula produces a distinct tank capacitor voltage calculation for each Helmholtz capacitance estimate. The Helmholtz capacitance estimates along with the calculated tank capacitor voltages are stored into main memory as a look-up table, and the actual, measured tank capacitor voltage is compared with the set of calculated tank capacitor voltages. Searching through the look-up table, the apparatus chooses the Helmholtz capacitance estimate as the empirical estimate which produced a calculated tank capacitor voltage that most closely resembles the measured tank capacitor voltage.

In another embodiment, a single empirical estimate for the Helmholtz capacitance is substituted into the one part of the formula, either into the exponential term or into the additive and constant terms. The remaining term(s) may be reduced algebraically to solve for the unknown Helmholtz capacitance value. If the resulting calculation of the Helmholtz capacitance value does not agree with the originally substituted empirical estimate, then an updated empirical estimate is substituted into the first term(s), and a new Helmholtz capacitance is calculated using the remaining term(s). If the resulting calculation of the Helmholtz capacitance value lies within an acceptable range of the originally substituted empirical estimate, then the measured Helmholtz capacity is determined as the final empirical estimate. Such an approximation is simple to compute using conventional circuitry and can conform to any arbitrary level of accuracy by iterating through the equation with progressively better estimates for the Helmholtz capacitance.

When the Helmholtz capacitance and Warburg resistance have been determined, a plurality of parameters of importance for analyzing and optimizing a pacing system may be calculated, including the current delivered to the cardiac tissue at any instantaneous point in time, the average current delivered to the cardiac tissue over the duration of the pulse, the total charge and the total energy delivered to the cardiac tissue and to the leads, and the Helmholtz potential after pacing polarization.

Thus, the present invention comprises a combination of features and advantages that enable it to substantially advance the art by providing an apparatus for gauging both the resistive and capacitive components of the Helmholtz layer. These and various other characteristics and advantages of the present invention will be readily apparent to those skilled in the art upon reading the following detailed description of the preferred embodiments of the invention and by referring to the accompanying drawings.

BRIEF DESCRIPTION OF THE DRAWINGS

A better understanding of the present invention can be obtained when the following detailed description of the preferred embodiment is considered in conjunction with the following drawings, in which:

Figure 1 illustrates the human heart;

Figure 2 shows the typical connections between a conventional pacer-defibrillator and the human heart;

Figure 3A is a known model of the Helmholtz circuit for a bipolar lead configuration;

Figure 3B is a known model of the Helmholtz circuit for a unipolar lead configuration;

Figure 4 is an exemplary block diagram of a cardiac stimulator made in accordance with the present invention;

Figure 5 is a block diagram of the impedance circuit and pulse generator circuit of the cardiac stimulator shown in Figure 4;

Figure 6 is a timing diagram showing the control signals asserted by the processor of the cardiac stimulator shown in Figure 4;

Figure 7 is a graph of the voltage across the tank capacitor of Figure 5 versus the Helmholtz voltage created in the heart tissue during cardiac stimulation; and

Figure 8 is a flowchart describing an alternative embodiment for estimating the Helmholtz voltage using the apparatus of Figure 5.

DETAILED DESCRIPTION OF PREFERRED EMBODIMENTS

An exemplary cardiac stimulator 400 made in accordance with the present invention is illustrated in the block diagram of Figure 4. The cardiac stimulator 400 may be a pacemaker, a defibrillator, or any or implantable cardiac stimulator. The cardiac stimulator 400 generally includes atrial and ventricular sense circuits 462 and 464, a processor 470, main memory 475, an impedance circuit 466, and a pulse generator 468, all housed in an enclosure, or "can" 401. The exemplary embodiment of Figure 4 shows cardiac stimulator 400 with four
15 led electrodes, namely atrial tip and ring electrodes 410 and 420, respectively, and ventricular ring and tip electrodes 440 and 450, respectively. Can 401 may function as an additional electrode in accordance with known techniques. The invention, however, may be practiced using any number of electrodes implanted in any chamber of the heart and in any configuration.

Referring still to Figure 4, electrodes 410 and 420 couple to the atrial sense circuit 462 via capacitors C1 and C2, respectively, which are preferably 0.15 microfarad (μF) capacitors. Similarly, electrodes 440 and 450 couple to the ventricular sense circuit 464 via capacitors C3 and C4, respectively, which are also preferably 0.15 μF capacitors. The atrial sense circuit 462 processes
25 signals received from the atrial chamber of the heart via the atrial electrodes 410 and 420, while the ventricular sense circuit 464 processes signals received from the ventricular chamber via the ventricular electrodes 440 and 450. The atrial and ventricular sense circuits 462 and 464 generally include a low power, highly sensitive amplifier, a band pass filter, and a threshold
30 detector (not shown). The atrial 462 and ventricular 464 circuits further include internal pulldown switches SW_A and SW_V , respectively, the states of which are controlled by the processor 470. The amplifier amplifies the

electrical signal from the associated electrodes, and the band pass filter attenuates signals whose frequencies are outside the range of frequencies known to correspond to cardiac signals. The threshold detector compares the amplified and filtered signal to a reference signal to determine when a cardiac event (also referred to as a "sense event") has occurred. If the magnitude of the amplified and filtered cardiac signal exceeds the reference signal, the processor 470 determines that a sense event has occurred. The processor 470 may then pace the heart based either on detecting or not detecting sense events via pulse generator 468 and electrodes 401, 410, 420, 440, and 450. For example, the processor 470 may initiate a ventricular pacing pulse if an atrial sense event has not been detected within a predetermined period of time following a previous atrial sense event.

Cardiac stimulator 400 further includes lead switches SW1 and SW2 as well as can switch SW3 for configuring unipolar and bipolar sensing modes and also unipolar and bipolar pacing modes, as described below. Switches SW1, SW2, and SW3 are preferably processor-controlled, single-pole single-throw (SPST) switches. When closed by the processor 470, the atrial lead switch SW1 couples the atrial ring electrode 420 to ground. Similarly, the ventricular lead switch SW2, when closed by the processor 470, couples the ventricular ring electrode 450 to ground. Can switch SW3, when closed by the processor 470, couples the can 401 to ground.

For atrial sensing using bipolar leads, atrial lead switch SW1, atrial internal pulldown switch SW_A, and can switch SW3 are all preferably open. In this configuration, the atrial sense circuit 462 receives a differential sense signal from tip 410 and ring 420 electrodes, respectively. For atrial sensing using a unipolar lead configuration, atrial lead switch SW1 remains open, but atrial internal pulldown switch SW_A and atrial can switch SW3 are preferably closed.

Ventricular sensing operates in substantially the same manner. For ventricular sensing using bipolar leads, ventricular lead switch SW2, ventricular internal pulldown switch SW_V, and can switch SW3 are all preferably open. In this configuration, the ventricular sense circuit 464

receives a differential sense signal from tip 440 and ring 450 electrodes, respectively. For ventricular sensing using a unipolar lead configuration, ventricular lead switch SW2 remains open, but ventricular internal pulldown switch SW_v and can switch SW3 are preferably closed.

5 The pulse generator 468 produces an appropriate electrical pulse to stimulate the desired chamber of the heart to beat. The processor 470 initiates the pulse generator 468 to produce a pacing pulse, and the pulse generator responds by delivering the pacing pulse to the desired chamber of the heart. The pulse generator 468 preferably includes a rate limiter to prevent the
10 processor 470 from erroneously pacing the heart at an excessively high rate. The pulse generator 468 preferably couples to the atrial tip electrode 410 via an atrial pulse line 480 in series with a DC-blocking series capacitor C5 and further couples to ventricular tip electrode 440 via a ventricular pulse line 485 in series with a DC-blocking series capacitor C6. Further, the pulse generator 468
15 couples to ground to provide a circuit return path for pacing pulses. Hence, the pulse generator 468 may send a pacing pulse to the atrial or ventricular chamber via atrial pulse line 480 or ventricular pulse line 485, respectively.

 In addition to selecting atrial or ventricular sensing, switches SW1, SW2, and SW3 configure the cardiac stimulator 400 for unipolar or bipolar pacing.
20 For atrial bipolar pacing, atrial lead switch SW1 is preferably closed (therefore coupled to ground), and can switch SW3 is open. This bipolar pacing configuration allows a pacing pulse issued to the atrial chamber via atrial pulse line 480 and atrial tip electrode 410 to complete a circuit path to the pulse generator 468 through atrial ring electrode 420, which couples to ground.
25 Ventricular bipolar pacing occurs in substantially the same manner, with ventricular lead switch SW2 closed (therefore coupled to ground) and can switch SW3 open. A pacing pulse issued to the ventricular chamber via ventricular pacing line 485 is then allowed to complete a circuit path to the pulse generator 468 through ventricular ring electrode 450, which couples to ground.

30 For unipolar stimulation, can switch SW3 is closed, and atrial lead switch SW1 (for stimulation of the atrial chamber) or ventricular lead switch SW2 (for stimulation of the ventricular chamber) is opened. In this unipolar pacing

configuration, a pacing pulse issued to the atrial chamber via atrial pacing line 480 and atrial tip electrode 410 is allowed to complete a circuit path to the pulse generator 468 via the can 410, which is coupled to ground. Similarly, a pacing pulse issued to the ventricular chamber via ventricular pacing line 485 and ventricular tip electrode 450 is allowed to complete a circuit path to the pulse generator 468 via the can 410, which is coupled to ground.

Main memory 475 couples to the processor 470 and is capable of storing program instructions and other data to be retrieved or updated by the processor 470. Accordingly, cardiac stimulator 400 may be programmed through instructions stored in main memory to operate in one of a number of pacing modes. For example, the cardiac stimulator 400 may be programmed to sense electrical activity in the atrium, and then to pace the ventricle following a predetermined time delay after the occurrence of an atrial sense event if the ventricle has not contracted on its own. Additionally, the processor 470 may be programmed to store sense data, impedance data, or other information in main memory 475 to be retrieved at a later date either by the processor 470 or by a physician.

Cardiac stimulator 400 uses an impedance circuit 466 to determine the electrical impedance of the lead and heart tissue circuit, as modeled by Figures 3A and 3B. The impedance circuit 466 generally processes the electrical signal from the pulse generator 468 and provides one or more output status signals to the processor 470. The processor 470 uses the status signal from the impedance circuit 466 to compute the impedance of the lead/heart tissue, as described in more detail below.

Figure 5 illustrates the electrical characteristics of the resistance of lead 505 combined with the impedance inherent in heart 250. Resistor R_L generally represents the combined resistance of the lead 505 and the heart 250, while C_L represents the Helmholtz capacitance described previously. Note that R_L and C_L do not depict actual components in the present invention but represent a model of the lead/heart tissue impedance to be determined. Cardiac stimulator 400 calculates lead/tissue resistance R_L and Helmholtz capacitance C_L in accordance with the methods described below. Referring still to Figure 5, a

preferred embodiment of a pulse generator 468 is shown coupled to heart 250 via lead 505. Pulse generator 468 comprises a voltage source V_i , a charge switch SW1, a pacing switch SW2, tank capacitor C_T , current-measurement-shunt resistor R_T , a discharge switch SW3, discharge resistor R_x , and DC-blocking capacitor C_B .

Voltage source V_i is any suitable voltage source for charging tank capacitor C_T . Voltage source V_i typically comprises a battery which may or may not be rechargeable and a programmable voltage multiplier. Voltage source V_i couples to charging switch SW1, which preferably is a single-pole/single-throw (SPST) switch controlled by a processor such as processor 470 in Figure 4, via a charge control signal 525. Tank capacitor C_T and shunt resistor R_T couple in series between charging switch SW1 and ground, with C_T connected directly to SW1 and R_T connected directly to ground. One terminal of pacing switch SW2 connects between charge switch SW1 and tank capacitor C_T while the other terminal of switch SW2 connects to a DC-blocking capacitor C_B , discharge switch SW3, and discharge resistor R_x . Pacing switch SW2 is preferably an SPST switch with an internal switch resistance R_{sw} . Processor 470 controls the state of pacing switch SW2 via a pace control signal 530. Switch SW3 likewise is a processor-controlled, SPST switch, coupling to the processor 470 via a discharge control signal 535. Discharge switch SW3 and discharge resistor R_x further couple in parallel and connect to ground. Discharge resistor R_x preferably has a very high resistance compared with shunt resistor R_T , switch resistance R_{sw} , and lead/tissue resistance R_L . A preferred embodiment includes a shunt resistor R_T of 22 Ω (ohms), a switch resistance R_{sw} of 10 Ω , a discharge resistor R_x of 100k Ω , and a typical lead/tissue resistance of 500 Ω .

Lead 505 couples to DC-blocking capacitor C_B and terminates to electrode 520 at the heart 250. While lead 505 preferably comprises either a bipolar or unipolar lead, it is illustrated in Figure 5 as a unipolar lead for simplicity. As one of ordinary skill in the art would recognize, the circuits of Figures 3A and 3B are substantially the same, since the ground node essentially serves as a lead substitute by providing a current path from the cardiac

stimulator 400 to the heart. Thus, the circuit of Figure 5 applies equally to both bipolar and unipolar lead configurations.

Impedance circuit 466 preferably comprises three sample-and-hold units U1, U2, and U3, as well as a pair of high-impedance buffers U4 and U5. Each buffer U4 and U5 may comprise any buffer circuit configured as a voltage follower with high-impedance inputs. The buffers U4 and U5 in the present embodiment are shown as unity-gain operational amplifiers (or "op-amps"), with each buffer output coupled directly to the inverting input (–) of the same buffer. Alternatively, the buffers may consist of any device that amplifies an input signal. The inverting inputs of buffers U4 and U5 connect to resistors R1 and R2, respectively, which also couple to ground. The noninverting input (+) of buffer U4 couples to tank capacitor C_T , charging switch SW1, and pacing switch SW2. The noninverting input of buffer U5 couples to the junction between tank capacitor C_T and shunt resistor R_T . The output of buffer U4 drives the input of sample-and-hold unit U1. The output of buffer U5 drives both sample-and-hold units U2 and U3.

The sample-and-hold units are controlled by the processor via signals sample1 540 (U1), sample2 545 (U2), and sample3 550 (U3). When a sample control signal 540, 545, or 550 is asserted or pulsed, the corresponding sample-and-hold unit instantaneously samples the voltage appearing on its input terminal and holds that voltage on its output terminal even after the input signal is changed or removed. As described below, the output signals from sample-and-hold units U1, U2, and U3 represent voltages measured in the pulse generator 468. In a preferred embodiment, voltages are sampled at specific times in relation to the pacing pulse. For a pacing pulse with a duration of T_{PW} seconds, sample-and-hold unit U3 will sample the shunt resistor voltage just after the beginning of the pacing pulse, sample-and-hold unit U2 will sample the shunt resistor voltage just before the end of the pacing pulse, and sample-and-hold unit U1 will sample the tank capacitor voltage following the pacing pulse. A more detailed explanation of these voltages readings is presented below, with respect to Figure 6. The high-impedance nature of buffers U4 and U5 insures

that the pulse generator 468 voltages are measured with negligible interference to the pulse generator 468.

Still referring to Figure 5, voltage source V_i charges tank capacitor C_T to a voltage substantially equivalent to V_i when the charging switch SW1 is closed.

5 When the charging switch SW1 and discharging switch SW3 are opened and pacing switch SW2 is subsequently closed, the tank capacitor C_T and shunt resistor R_T are effectively switched into a resistive-capacitive (or "RC") charging circuit including switch resistance R_{SW} , discharge resistor R_X , DC-blocking capacitor C_B , lead/tissue resistance R_L , and Helmholtz capacitance C_L . Thus,

10 the charge stored in C_T discharges into R_T , R_{SW} , R_X , C_B , R_L , and C_L .

Figure 6 illustrates a detailed timing diagram of the control signals **sample1**, **sample2**, **sample3**, **pace**, **discharge**, and **charge** which are asserted by the processor 470 of Figure 5 to control the pulse generator 468 and impedance circuit 466. In the diagram of Figure 6, the pacing pulse begins

15 at $t = 0$ and preferably extends for a duration of T_{PW} seconds. Prior to the beginning of the pacing pulse, the charge and discharge signals are held low, or asserted, causing the charging switch SW1 and discharging switch SW3 to close. Also prior to the beginning of the pacing pulse, the pace signal is held high, or deasserted, causing the pacing switch SW2 to open. Thus, the tank

20 capacitor C_T charges to V_i volts. In a preferred embodiment, **sample1**, **sample2**, and **sample3** remain low prior to the beginning of the pacing pulse at time $t = 0$, indicating that the previous samples are being held at the outputs of sample-and-hold units U1, U2, and U3. The tank capacitor C_T becomes sufficiently charged prior to time $t = 0$, and the processor 470 deasserts the

25 charge and discharge signals at points 600 and 605, respectively.

The pacing pulse begins at time $t = 0$ when the processor 470 asserts the pace signal (point 610) to a logic low state, allowing charge from the tank capacitor C_T to begin flowing into the lead/tissue circuit. At time $t = 0^+$, which preferably is less than 10 μ s after time $t = 0$, the processor 470 pulses **sample3**

30 (point 615), causing sample-and-hold unit U3 to record the voltage $V_{RT}(0^+)$ across the shunt resistor R_T . The tank capacitor C_T continues to discharge until the end of the pacing pulse at time $t = T_{PW}$, which is marked by point 630. At

time $t = T_{PW}^-$, however, which preferably occurs approximately 10 s or less before time $t = T_{PW}$, the processor 470 pulses **sample2** (point 620), causing sample-and-hold unit U2 to record the voltage $V_{RT}(T_{PW}^-)$ across the shunt resistor.

5 At time $t = T_{PW}$, the processor 470 halts the pacing pulse by deasserting the **pace** signal (point 630) to a logic high state. Subsequently, the electric charge accumulated in the DC-blocking capacitor C_B and the Helmholtz layer (represented by C_L) begins to discharge to ground through the discharge resistor R_X . In alternative embodiments, the processor pulses **sample1** (point 10 635) at time T_{PW}^+ , which preferably occurs approximately 10 s or less after time $t = T_{PW}$. Next, the processor 470 asserts the **discharge** and **charge** signals at points 640 and 645, respectively. The **discharge** signal allows any electric charge remaining in the DC-blocking capacitor C_B and Helmholtz layer (C_L) to quickly discharge, while the **charge** signal causes voltage source V_I to 15 charge tank capacitor C_T in preparation for delivering the next pacing pulse.

Any capacitor behaves as a short-circuit for a short time after current is applied to that capacitor. Thus, immediately after tank capacitor C_T and shunt resistor R_T are switched into the charging circuit, or at time $t = 0^+$, the current in the charging circuit equals the voltage held by C_T divided by the resistance 20 presented by the resistive circuit of R_X , R_T , R_{SW} , and R_L . At the same time, processor 470 asserts control signal **sample3**, causing sample-and-hold unit U3 to sample and hold the voltage drop $V_{RT}(0^+)$ across shunt resistor R_T . Because the voltage drop across any resistor is proportional to the current flowing through that resistor, the voltage $V_{RT}(0^+)$ can be used to determine the current flowing 25 through the charging circuit. It follows that the lead/tissue resistance R_L can be calculated using equation (1) below:

$$R_L = - \frac{R_X}{\frac{R_X}{R_T \left(\frac{V_I}{V_{RT}(0^+)} + 1 \right) + R_{SW}} + 1} \quad (1)$$

When a constant voltage is applied to an RC circuit, the amount of current flowing through that circuit changes over time in a well-documented 30 manner. Thus, as the charge contained in tank capacitor C_T is released into the

charging circuit from time $t = 0$ to time $t = T_{PW}$, the charging current changes over time. The rate at which the current changes is determined by the resistances R_T , R_{SW} , and R_L and capacitances C_T , C_B , and C_L .

Because the voltage drop across the shunt resistor at any point in time $V_{RT}(t)$ is directly proportional to the current through R_T and because the resistances R_T , R_{SW} , and R_L and capacitances C_T , C_B , and C_L uniquely determine the charging current at time $t = T_{PW}^-$, the Helmholtz capacitance C_L may be calculated using equation (2) below. Because R_X has a very high impedance compared with the remaining components in the circuit, little current flows through R_X . Thus, the presence of R_X may be neglected for purposes of analyzing the Helmholtz capacitance C_L .

$$C_L = - \frac{C_T C_B}{C_T C_B \frac{R_T + R_{SW} + R_L}{T_{PW}} \ln \left(- \frac{V_{RT}(T_{PW}^-) (R_T + R_{SW} + R_L)}{V_T R_T} \right) + C_B + C_T} \quad (2)$$

where $\ln()$ is the natural logarithm function.

Following the charging pulse, sample-and-hold units U3 and U2 hold voltages $V_{RT}(0^+)$ and $V_{RT}(T_{PW}^-)$, respectively. Using these measured values of $V_{RT}(0^+)$ and $V_{RT}(T_{PW}^-)$ along with known values of C_T , R_T , and R_{SW} , the processor 470 calculates the lead/tissue resistance R_L and the Helmholtz capacitance C_L using equations (1) and (2), above. These calculations provide an accurate characterization of the lead/tissue impedance and assist physicians in monitoring lead integrity, device longevity, and current, charge, and energy delivered to the heart tissue.

The pulse generator 468 operates as described previously, and the processor 470 asserts **sample3** at time $t = 0^+$ to measure the shunt resistor voltage $V_{RT}(0^+)$ at the beginning of the pulse period. Shortly after time $t = T_{PW}$, or at time $t = T_{PW}^+$, the processor 470 asserts the **sample1** control signal to cause and sample-and-hold unit U1 to record the voltage of tank capacitor C_T via buffer U4 immediately following the pulse period. The time $t = T_{PW}^+$ is preferably less than 10 μ s after time $t = T_{PW}$. The tank capacitor voltage at time $t = T_{PW}^+$, or $V_{CT}(T_{PW}^+)$, represents the voltage across tank capacitor C_T with respect to ground shortly after the pulse period. The measurement of $V_{RT}(0^+)$ allows the processor 470 to calculate the lead/tissue resistance R_L as before,

using equation (1). In the alternative embodiment, however, the processor 470 uses $V_{CT}(T_{PW}^*)$ in equation (3), below, to estimate the Helmholtz capacitance C_L either by generating a lookup table or by successive approximation, as will be explained below with respect to Figures 8A and 8B. Equation (3) governs the tank capacitor voltage at time $t = T_{PW}^*$:

$$V_{CT}(T_{PW}^*) = \frac{V_i(C_T C_B + C_T C_L)}{C_T C_B + C_T C_L + C_B C_L} + V_i \left(1 - \frac{C_T C_B + C_T C_L}{C_T C_B + C_T C_L + C_B C_L} \right) e^{-\left(\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L} \right) T_{PW}^*} \quad (3)$$

where e is the base of the natural logarithm.

Figure 7 illustrates a graph of $V_{CT}(T_{PW}^*)$ versus C_L , according to equation (3). Note that for any point on the graph, an increase in Helmholtz capacitance C_L results in a decrease in $V_{CT}(T_{PW}^*)$. For example, point 700 represents $C_L = 10 \mu F$, $V_{CT}(T_{PW}^*) = 4.06$. It can be seen that for any $C_L > 10 \mu F$, $V_{CT}(T_{PW}^*) < 4.06$. For instance, $C_L = 15 \mu F$ and $V_{CT}(T_{PW}^*) = 4.02$ at point 705. Thus, $V_{CT}(T_{PW}^*)$ of equation (3) is said to monotonically decrease in Helmholtz capacitance C_L . It follows that any measured tank capacitor voltage $V_{CT}(T_{PW}^*)$ corresponds to a unique Helmholtz capacitance C_L which may be calculated using the alternative embodiments presented herein.

After the processor 470 calculates the lead/tissue resistance R_L using shunt resistor voltage measurement $V_{RT}(0^*)$ in equation (1), all the variables in equation (3) are known except for the Helmholtz capacitance C_L . To determine C_L , note that the right-hand side of equation (3) consists of an additive term $A =$

$$\frac{V_i(C_T C_B + C_T C_L)}{C_T C_B + C_T C_L + C_B C_L}, \text{ a constant term } K = V_i \left(1 - \frac{C_T C_B + C_T C_L}{C_T C_B + C_T C_L + C_B C_L} \right), \text{ and}$$

$$\text{an exponential term } E = e^{-\left(\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L} \right) T_{PW}^*}.$$

Because the Helmholtz capacitance C_L is present in the additive, constant, and exponential terms in equation (3), there is no explicit algebraic solution for C_L . Hence, in one alternative embodiment, the processor 470 either generates or retrieves from memory a set of candidate estimates for Helmholtz capacitance C_L . The processor then evaluates the right-hand-side of equation (3) using each of the candidate estimates, recording the evaluation results into memory as a lookup table. The processor 470 estimates C_L by determining which evaluation of equation (3)

most closely matches the voltage $V_{CT}(T_{PW}^*)$ at the output of sample-and-hold unit U1. Because $V_{CT}(T_{PW}^*)$ in equation (3) decreases monotonically in C_L , the value of C_L used in equation (3) to compute the $V_{CT}(T_{PW}^*)$ which most closely matches the $V_{CT}(T_{PW}^*)$ measured from U1 is a good estimate of the actual
5 Helmholtz capacitance, C_L . Further, the processor 470 may be programmed to estimate the Helmholtz capacitance to any arbitrary degree of accuracy in this embodiment by evaluating equation (3) using numerous candidate values of C_L which are sufficiently closely spaced.

Table I illustrates an exemplary lookup table
10 using this alternative embodiment. To generate Table I, processor 470 uses known values of V_i , C_T , C_B , R_T , R_{SW} , and T_{PW} which have been previously stored in processor memory. For purposes of this example, these values are $V_i = 5$ V, $C_T = 10$ μ F, $C_B = 10$ μ F, $R_T = 22$ Ω , $R_{SW} = 17$ Ω , and $T_{PW}^* = 1.5$ ms. Also, a set of candidate values for C_L has been stored into the processor 470. For
15 purposes of this example, these values are 1 μ F, 2 μ F, 3 μ F, 4 μ F, 5 μ F, 6 μ F, 7 μ F, 8 μ F, 9 μ F, and 10 μ F. Assuming also for this example that the processor uses the output of sample-and-hold unit U3 to calculate the lead/tissue resistance $R_L = 500$ Ω , the processor evaluates equation (3) using each of the candidate values of C_L . Table I illustrates the resulting calculations of $V_{CT}(T_{PW}^*)$
20 as a function of the candidate C_L values.

Table I: Example lookup table calculated from equation (3) and used to estimate C_L .

| C_L (candidate) | $V_{CT}(T_{PW}^*)$ (calculated) |
|----------------------|------------------------------------|
| 1 μF | 4.5981 V |
| 2 μF | 4.3875 V |
| 3 μF | 4.2750 V |
| 4 μF | 4.2065 V |
| 5 μF | 4.1606 V |
| 6 μF | 4.1279 V |
| 7 μF | 4.1033 V |
| 8 μF | 4.0843 V |
| 9 μF | 4.0690 V |
| 10 μF | 4.0565 V |

5 In this example, the processor 470 measures from sample-and-hold unit U1 the actual tank capacitor voltage after the pulse, or $V_{CT}(T_{PW}^*)$, as 4.08 V. Scanning through the lookup table, the processor determines that the measured value of $V_{CT}(T_{PW}^*)$ most closely matches the lookup table value 4.0843 V. Because $C_L = 8 \mu F$ corresponds to $V_{CT}(T_{PW}^*) = 4.0843$, the processor
10 determines C_L to be 8 μF in this example. Note that the impedance values, voltages, pulse width, and candidate C_L values described herein are used only for this example and are not intended to limit the present invention. Furthermore, a lookup table of this embodiment may have any number and range of candidate C_L values and should not be limited to the candidate C_L
15 values presented in the example.

In another alternative embodiment, the processor 470 calculates the lead/tissue resistance R_L and measures the tank capacitor voltage following the pacing pulse $V_{CT}(T_{PW}^*)$ as before. In this embodiment, however, the processor uses equation (3) to iteratively estimate the Helmholtz capacitance C_L . First, the

processor 470 substitutes an empirical estimate, preferably greater than the largest possible Helmholtz capacitance C_L , into the exponential term of equation (3). The processor then solves for an approximation of C_L in the additive and constant terms. If the empirical estimate of C_L agrees closely with the calculated approximation, then the processor uses the calculated approximation for the Helmholtz impedance.

The flowchart of Figure 8 illustrates the steps of successive approximation involved in this embodiment if the processor inserts the empirical estimate of C_L into the exponential term of equation (3) and solves for an approximation of C_L using the additive and constant terms. The flowchart begins at the "start" block. Moving to block 800, the processor 470 computes

the value of the exponential term $E = e^{\frac{\left(\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L(\text{empirical})}\right) T_{PW}}{R_T + R_{SW} + R_L}}$ using an initial empirical estimate of C_L , or $C_L(\text{empirical})$, that is preferably larger than the largest possible C_L value. Using the calculated E , equation (3) may be expressed as in equation (4), below, which permits solving for C_L algebraically.

$$V_{Cr}(T_{PW}^+) = \frac{V_i(C_T C_B + C_T C_L)}{C_T C_B + C_T C_L + C_B C_L} + V_i \left(1 - \frac{C_T C_B + C_T C_L}{C_T C_B + C_T C_L + C_B C_L} \right) E \quad (4)$$

In block 805, the processor 470 solves equation (4) algebraically for C_L , resulting in an approximation of the Helmholtz capacitance $C_L(\text{approx})$. The algebraic solution for C_L in equation (4) is given by $C_L(\text{approx})$ in equation (5):

$$C_L(\text{approx}) = \frac{C_T C_B (V_i - V_{Cr}(T_{PW}^+))}{(C_T + C_B) V_{Cr}(T_{PW}^+) - V_i C_T - V_i E C_B} \quad (5)$$

In block 810, the processor computes the absolute difference between $C_L(\text{empirical})$ and $C_L(\text{approx})$; or $|C_L(\text{empirical}) - C_L(\text{approx})|$. If the absolute difference between $C_L(\text{empirical})$ and $C_L(\text{approx})$ is greater than a predetermined limit Δ_{CL} , which is preferably $\Delta_{CL} = 1 \mu\text{F}$, then the processor 470 moves to block 815 and adjusts the empirical estimate $C_L(\text{empirical})$ so that the absolute difference between $C_L(\text{empirical})$ and $C_L(\text{approx})$ is smaller during a subsequent iteration. Because of the nature of this procedure, equation (5) always produces a value of $C_L(\text{approx})$ that is between $C_L(\text{empirical})$ and the true Helmholtz capacitance. Thus, $C_L(\text{empirical})$ is preferably adjusted by

setting $C_L(\text{empirical})$ equal to $C_L(\text{approx})$, although other known methods of adjusting $C_L(\text{empirical})$ so that $C_L(\text{empirical})$ and $C_L(\text{approx})$ converge iteratively may be used as well. When $C_L(\text{empirical})$ is adjusted to produce a new $C_L(\text{empirical})$ in step 815, the processor 470 repeats steps 800, 805, 810, and
5 815 of the flowchart until $C_L(\text{approx})$ is within the predetermined limit Δ_{CL} of $C_L(\text{empirical})$.

Next moving to step 820, the processor 470 determines if $C_L(\text{empirical})$ is greater than $C_L(\text{approx})$. If $C_L(\text{empirical})$ is greater than $C_L(\text{approx})$ in step 820, then the current $C_L(\text{empirical})$ is larger than the true Helmholtz capacitance, and
10 the processor moves to step 825. In step 825, $C_L(\text{empirical})$ is preferably adjusted by subtracting Δ_{CL} from $C_L(\text{empirical})$. Moving next to step 830, the processor 470 computes the value of the exponential term E as in step 800, using the updated $C_L(\text{empirical})$. From the calculated E , equation (3) may be expressed as in equation (4), which permits solving for C_L algebraically. Hence,
15 in block 835, the processor 470 solves equation (4) algebraically for C_L to obtain an updated $C_L(\text{approx})$. As in step 805, the algebraic solution for C_L in step 835 is given by $C_L(\text{approx})$ in equation (5).

Next moving to step 840, the processor 470 determines if $C_L(\text{empirical})$ is less than or equal to $C_L(\text{approx})$. Because step 835 always results in a
20 $C_L(\text{approx})$ that is between $C_L(\text{empirical})$ and the true Helmholtz capacitance, the condition $C_L(\text{empirical}) \leq C_L(\text{approx})$ indicates that the previous adjustment of $C_L(\text{empirical})$ in step 825 resulted in a $C_L(\text{empirical})$ which was less than or equal to the true Helmholtz capacitance. Accordingly, $C_L(\text{empirical})$ is guaranteed to be within Δ_{CL} below the true Helmholtz capacitance, and
25 $C_L(\text{approx})$ is guaranteed to be between $C_L(\text{empirical})$ and the true Helmholtz capacitance. The processor thus moves to step 845, where the Helmholtz capacitance is estimated as $C_L = C_L(\text{approx})$. Alternatively, the Helmholtz capacitance may be estimated using the previous value of $C_L(\text{approx})$, which is guaranteed to be within Δ_{CL} above the true Helmholtz capacitance. If
30 $C_L(\text{empirical}) > C_L(\text{approx})$ in step 840, however, then the processor repeats back to step 825 to further adjust $C_L(\text{empirical})$.

Again examining step 820, if $C_L(\text{empirical}) \leq C_L(\text{approx})$, then $C_L(\text{empirical})$ is less than or equal to the true Helmholtz capacitance, and the processor moves to step 850. From step 850, the processor 470 compares $C_L(\text{empirical})$ to $C_L(\text{approx})$. If $C_L(\text{empirical}) = C_L(\text{approx})$, then both
 5 $C_L(\text{empirical})$ and $C_L(\text{approx})$ are equal to the true Helmholtz capacitance, and the processor 470 preferably estimates the Helmholtz capacitance as $C_L(\text{approx})$ in step 845. Alternatively, the processor 470 estimates the Helmholtz capacitance as $C_L(\text{empirical})$ in step 845. In addition, the Helmholtz capacitance may be estimated in step 845 as either the current or previous
 10 value of $C_L(\text{empirical})$, since these values are guaranteed to be within Δ_{CL} of the true Helmholtz capacitance. If $C_L(\text{empirical})$ is not equal to $C_L(\text{approx})$ in step 850, then the processor 470 moves to step 855. Steps 855 through 870 correspond approximately to steps 825 through 840, except that $C_L(\text{empirical})$ is assumed to be less than the true Helmholtz capacitance in steps 855 through
 15 870 and is therefore adjusted in step 855 by adding Δ_{CL} to $C_L(\text{empirical})$.

Following step 855, the processor 470 moves to step 860 to compute the value of the exponential term E as in step 800, using the updated $C_L(\text{empirical})$. From the calculated E , equation (3) may be expressed as in equation (4), which permits solving for C_L algebraically. Hence, in block 865, the processor 470
 20 solves equation (4) algebraically for C_L to obtain an updated $C_L(\text{approx})$. As in step 805, the algebraic solution for C_L in step 865 is given by $C_L(\text{approx})$ in equation (5).

Next moving to step 870, the processor 470 determines if $C_L(\text{empirical})$ is greater than or equal to $C_L(\text{approx})$. Because step 865 always results in a
 25 $C_L(\text{approx})$ that is between $C_L(\text{empirical})$ and the true Helmholtz capacitance, the condition $C_L(\text{empirical}) \geq C_L(\text{approx})$ indicates that the previous adjustment of $C_L(\text{empirical})$ in step 855 resulted in a $C_L(\text{empirical})$ which was greater than or equal to the true Helmholtz capacitance. Accordingly, $C_L(\text{empirical})$ is guaranteed to be within Δ_{CL} above the true Helmholtz capacitance, and
 30 $C_L(\text{approx})$ is guaranteed to be between $C_L(\text{empirical})$ and the true Helmholtz capacitance. The processor thus moves to step 845, where the Helmholtz capacitance is estimated as $C_L = C_L(\text{approx})$. Alternatively, the Helmholtz

capacitance may be estimated using the previous value of C_L (approx), which is guaranteed to be within c_L below the true Helmholtz capacitance. In addition, the Helmholtz capacitance may be estimated in step 845 as either the current or previous value of C_L (empirical), since these values are guaranteed to be within ΔC_L of the true Helmholtz capacitance. If C_L (empirical) < C_L (approx) in step 870, however, then the processor repeats back to step 855 to further adjust C_L (empirical).

When the Helmholtz capacitance C_L and load resistance R_L have been determined, a plurality of parameters of importance for analyzing and optimizing a pacing system may be calculated, including the current delivered to the cardiac tissue at any instantaneous point in time, the average current delivered to the cardiac tissue over the duration of the pulse, the total charge and the total energy delivered to the cardiac tissue and to the leads, and the Helmholtz potential after pacing polarization. For instance, the current flowing through the heart tissue at time t , or $i_L(t)$, is given by equation (6), neglecting R_X :

$$i_L(t) \approx \frac{v_i}{R_T + R_{SW} + R_L} e^{-\left(\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L}\right)t} \quad (6)$$

where e is the base of the natural logarithm.

Neglecting R_X as before, equation (7) represents the average current flowing through the heart tissue:

$$\bar{i}_L \approx \frac{v_i}{T_{PW} \left(\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L} \right)} \left[1 - e^{-\left(\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L}\right)T_{PW}} \right] \quad (7)$$

where e is the base of the natural logarithm.

Again neglecting R_X , equation (8) represents the charge Q_D delivered to the heart tissue from time $t = 0$ to time $t = T_{PW}$:

$$Q_D \approx \frac{v_i}{\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L}} \left[1 - e^{-\left(\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L}\right)T_{PW}} \right] \quad (8)$$

where e is the base of the natural logarithm.

Finally, the energy J_D delivered to the heart tissue from time $t = 0$ to time $t = T_{PW}$, neglecting R_X as before, is given by equation (9):

$$J_D \approx \frac{v_i^2 R_L}{2(R_T + R_{SW} + R_L) \left[\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L} \right]} \left[1 - e^{\frac{-1 \left(\frac{1}{C_T} + \frac{1}{C_B} + \frac{1}{C_L} \right) T_{PW}}{R_T + R_{SW} + R_L}} \right] + \frac{Q_D^2}{2C_L} \quad (9)$$

Thus, the present invention produces a very accurate impedance
 5 characterization of the lead/tissue interface, including both resistive and reactive
 impedance components. Further, since buffers U4 and U5 have high-
 impedance inputs coupled directly to the pulse generator 468, the present
 invention is adapted to perform impedance measurements during normal pacing
 and defibrillating operation and with minimal interference to the pulse generator
 10 468. In addition, and importantly, because the impedance measurements occur
 during normal pacer operation, the pacer operation need not be suspended in
 order to collect impedance data.

Because the processor 470 controls the switches SW1, SW2, and SW3
 and also the sample signals, the processor 470 may be easily programmed to
 15 calculate lead/tissue impedance whenever desired. For instance, the processor
 470 may calculate the lead/tissue impedance during every n^{th} pacing pulse,
 where n can be an arbitrary integer. The periodic impedance calculations can
 then be stored into main memory to be retrieved at a later date, perhaps by a
 physician who needs to verify or optimize the implantable device 400. Storing
 20 the calculations in memory also allows the processor 470 to perform statistical
 analyses which are useful for pacer maintenance, such as calculating minimum
 impedance measurements, maximum impedance measurements, and moving
 averages. In addition, if the implantable device 400 is capable of external
 control through telemetry with a device external to the body, the processor 470
 25 can easily be programmed to calculate lead impedance during manually-
 induced test sequences. Hence, physicians have access to both long-term and
 immediate impedance data with which to optimize and maintain the implanted
 device.

The alternative embodiments described above allow the processor 470 to
 30 accurately calculate both the lead/tissue resistance R_L as well as the Helmholtz

capacitance C_L to any arbitrary degree of accuracy. Further, the alternative embodiments do not require measurement of the shunt resistor voltage $V_{CT}(T_{PW}^-)$ just prior to the end of the pulse at time $t = T_{PW}^-$.

5 Numerous variations and modifications will become apparent to those skilled in the art once the above disclosure is fully appreciated. It is intended that the following claims be interpreted to embrace all such variations and modifications.

What is claimed is:

1. An implantable apparatus for measuring the Helmholtz capacitance comprising:
an impedance circuit; and
a processor coupled to said impedance circuit and receiving from
5 said impedance circuit at least one signal from which the Helmholtz capacitance is determined.
2. The apparatus of claim 1 wherein:
said apparatus further comprises a pulse generator coupled to
10 said impedance circuit and including a resistor;
said impedance circuit includes a buffer receiving a voltage associated with said resistor and a sample-and-hold receiving an output signal from said buffer; and
said processor generates a control signal for operating said
15 sample-and-hold.
3. The apparatus of claim 2 wherein said at least one signal from which the Helmholtz capacitance is determined includes the voltage from said sample-and-hold.
20
4. The apparatus of claim 3 wherein said pulse generator generates a current pulse during a pacing interval, said processor asserts said control signal within a predetermined time period before the end of said pacing interval, and said sample-and-hold provides a voltage
25 approximately equal to the voltage across said resistor at approximately the same time said processor asserts said control signal.
5. The apparatus of claim 4 wherein the Helmholtz capacitance is determined from an equation which relates the Helmholtz capacitance to
30 the voltage provided by said sample-and-hold.

6. The apparatus of claim 1 wherein:
said apparatus further comprises a pulse generator coupled to
said impedance circuit and including a capacitor;
said impedance circuit includes a buffer receiving a voltage
5 associated with said capacitor and a sample-and-hold receiving an
output signal from said buffer; and
said processor generates a control signal for operating said
sample-and-hold.
- 10 7. The apparatus of claim 6 wherein said at least one signal from
which the Helmholtz capacitance is determined includes the voltage from
said sample-and-hold.
8. The apparatus of claim 7 wherein said pulse generator generates
15 a current pulse during a pacing interval, said processor asserts said
control signal within a predetermined time period after the end of said
pacing interval, and said sample-and-hold provides a voltage
approximately equal to the voltage across said capacitor at
approximately the same time said processor asserts said control signal.
- 20 9. The apparatus of claim 8 wherein the Helmholtz capacitance is
determined from an equation which relates the Helmholtz capacitance to
the voltage provided by said sample-and-hold.
- 25 10. The apparatus of claim 9 wherein an empirical voltage is
determined using an empirical estimate $C_L(\text{empirical})$ of the Helmholtz
capacitance.
- 30 11. The apparatus of claim 10 wherein additional empirical voltage
values are determined based on additional empirical estimates
 $C_L(\text{empirical})$.

12. The apparatus of claim 11 wherein the Helmholtz capacitance is determined to be the empirical estimate $C_L(\text{empirical})$ which is associated with the empirical voltage that is closest to the voltage provided by said sample-and-hold.
- 5
13. The apparatus of claim 9 wherein an approximate estimate of the Helmholtz capacitance $C_L(\text{approx})$ is determined by substituting an empirical estimate of the Helmholtz capacitance $C_L(\text{empirical})$ into one portion of said equation and solving said equation for the Helmholtz
- 10 capacitance.
14. The apparatus of claim 13 wherein said $C_L(\text{empirical})$ is adjusted.
15. The apparatus of claim 13 wherein if said $C_L(\text{approx})$ is within a
- 15 predetermined range of said $C_L(\text{empirical})$, then the Helmholtz capacitance is estimated as said $C_L(\text{approx})$.
16. An implantable apparatus for measuring resistance of a lead/tissue interface, comprising:
- 20 an impedance circuit; and
- a processor coupled to said impedance circuit and receiving from said impedance circuit at least one signal from which said lead/tissue resistance is determined.
- 25 17. The apparatus of claim 16 wherein:
- said apparatus further comprises a pulse generator coupled to said impedance circuit and including a shunt resistor;
- said impedance circuit includes a buffer receiving a voltage associated with said shunt resistor and a sample-and-hold receiving an
- 30 output signal from said buffer; and
- said processor generates a control signal for operating said sample-and-hold.

18. The apparatus of claim 17 wherein said at least one signal from which lead/tissue resistance is determined includes the voltage from said sample-and-hold.

5 19. The apparatus of claim 18 wherein said pulse generator generates a current pulse during a pacing interval, said processor asserts said control signal within a predetermined time period after the start of said pacing interval, and said sample-and-hold provides a voltage approximately equal to the voltage across said shunt resistor at
10 approximately the same time said processor asserts said control signal.

20. The apparatus of claim 19 wherein said lead/tissue resistance is determined from an equation which relates the lead/tissue resistance to the voltage provided by said sample-and-hold.

15

21. A method for determining the pacing impedance of an implantable device, comprising:

- (a) determining the lead/tissue resistance; and
- (b) using said lead/tissue resistance determined in step (a) to

20 determine the Helmholtz capacitance.

22. The method of claim 21 wherein step (a) comprises:

- (a1) applying a voltage V_i to a closed-loop current path comprising a lead, heart tissue, and components of known impedance;
- 25 (a2) measuring a voltage produced in said circuit by said voltage V_i shortly after applying said voltage V_i to said circuit; and
- (a3) calculating said lead/tissue resistance based on the voltage measured in step (a2).

30 23. The method of claim 22 wherein step (a2) includes measuring a voltage across a resistor.

24. The method of claim 23 in which said lead/tissue resistance is calculated using a formula which includes said voltage across a resistor.

25. A method as in claim 21 wherein step (b) comprises:

- 5 (b1) applying a voltage V_i for a fixed amount of time, T_{PW} seconds, to a closed-loop current path comprising a lead, heart tissue, and components of known impedance;
- (b2) measuring a voltage produced in said closed-loop current path by said voltage V_i at a time $t = T_{PW^-}$, said time $t = T_{PW^-}$ occurring just
10 before time $t = T_{PW}$.
- (b3) calculating the Helmholtz capacitance based on the voltage measured in step (b2).

26. A method as in claim 25 wherein the Helmholtz capacitance is
15 calculated using a formula which includes the voltage measured in step (b2).

27. A method as in claim 21 wherein step (b) comprises:

- (b1) discharging a tank capacitor for a duration of T_{PW} seconds
20 through a closed-loop current path comprising a lead, heart tissue, and components of known impedance;
- (b2) measuring a voltage across said tank capacitor at time $t = T_{PW^+}$, just after the end of said duration of T_{PW} seconds.
- (b3) estimating the Helmholtz capacitance.

25

28. A method as in claim 27 wherein step (b3) includes calculating an empirical voltage value across said tank capacitor based on a predetermined empirical estimate of the Helmholtz capacitance $C_L(\text{empirical})$.

30

29. A method as in claim 28 wherein step (b3) further includes calculating additional empirical voltage values across said tank capacitor based on additional empirical estimates of the Helmholtz capacitance $C_L(\text{empirical})$.
- 5 30. A method as in claim 29 wherein step (b3) further includes estimating the Helmholtz capacitance to be the empirical estimate $C_L(\text{empirical})$ which is associated with the empirical voltage that is closest to said voltage across said tank capacitor at time $t = T_{PW} +$
- 10 measured in step (b2).
31. A method as in claim 27 wherein step (b3) comprises estimating the Helmholtz capacitance approximates said voltage across said tank capacitor using an equation which includes the Helmholtz capacitance.
- 15 32. A method as in claim 31 including substituting said empirical estimate $C_L(\text{empirical})$ into a first portion of said equation and solving said equation for the Helmholtz capacitance to obtain an approximate estimate $C_L(\text{approx})$ of the Helmholtz capacitance.
- 20 33. A method as in claim 32 including comparing said empirical estimate $C_L(\text{empirical})$ to said approximate estimate $C_L(\text{approx})$.
34. A method as in claim 33 including adjusting said empirical
- 25 estimate $C_L(\text{empirical})$.
35. A method as in claim 33 including estimating the Helmholtz capacitance to be said empirical estimate $C_L(\text{empirical})$ if said empirical estimate $C_L(\text{empirical})$ is within a predetermined range of said
- 30 approximate estimate $C_L(\text{approx})$.
36. A method as in claim 33 including estimating the Helmholtz capacitance to be said approximate estimate $C_L(\text{approx})$ if said empirical

estimate $C_L(\text{empirical})$ is within a predetermined range of said approximate estimate $C_L(\text{approx})$.

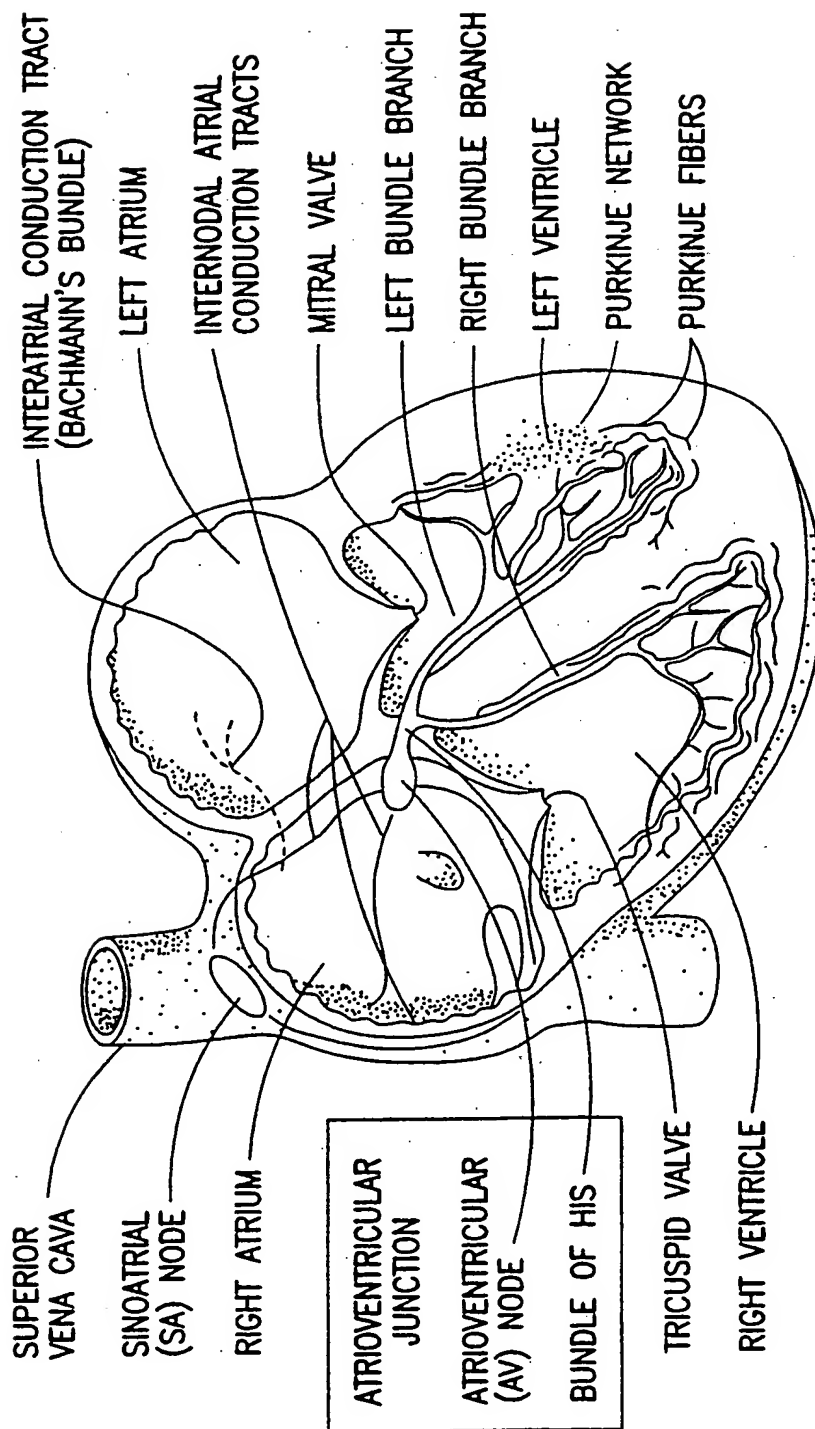


FIG. 1 (PRIOR ART)

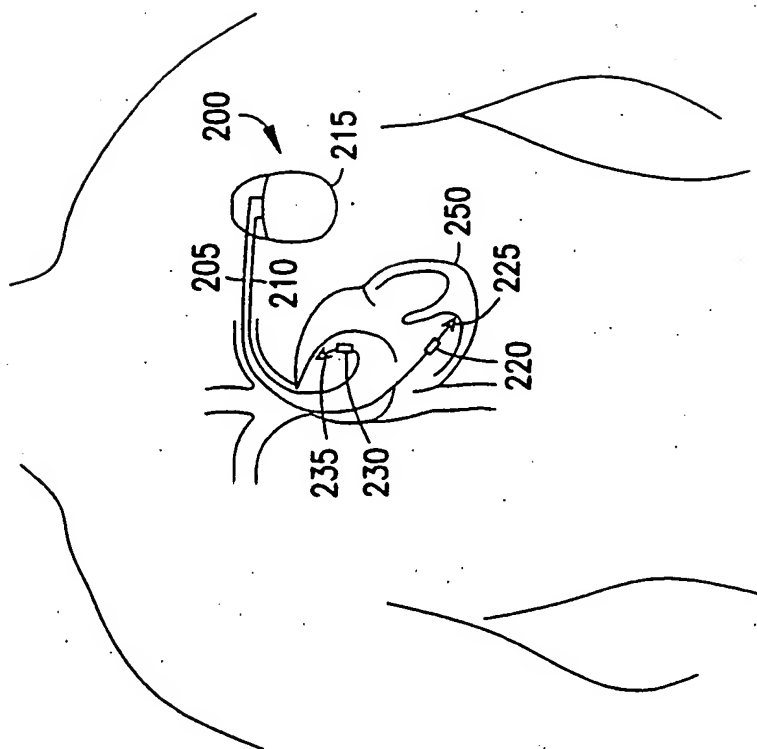


FIG. 2 (PRIOR ART)

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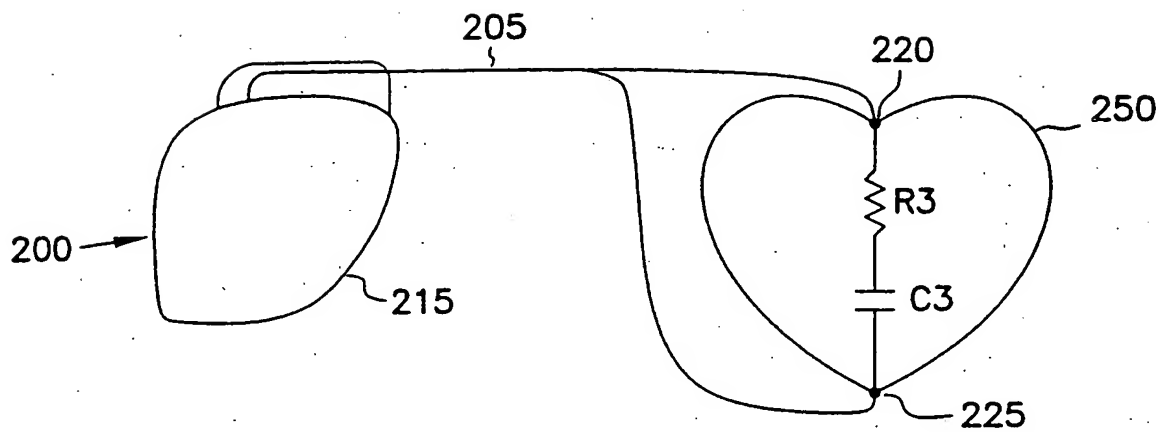


FIG. 3A (PRIOR ART)

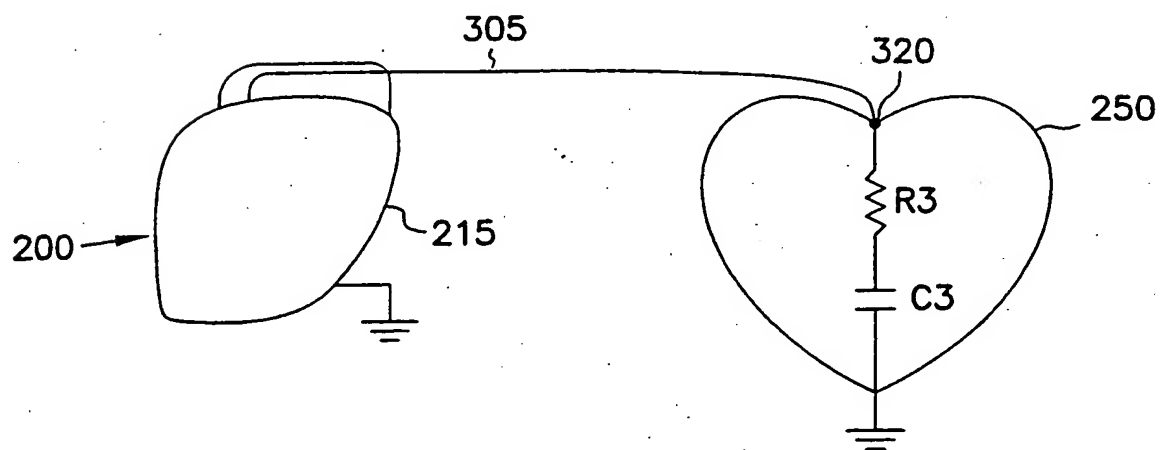


FIG. 3B (PRIOR ART)

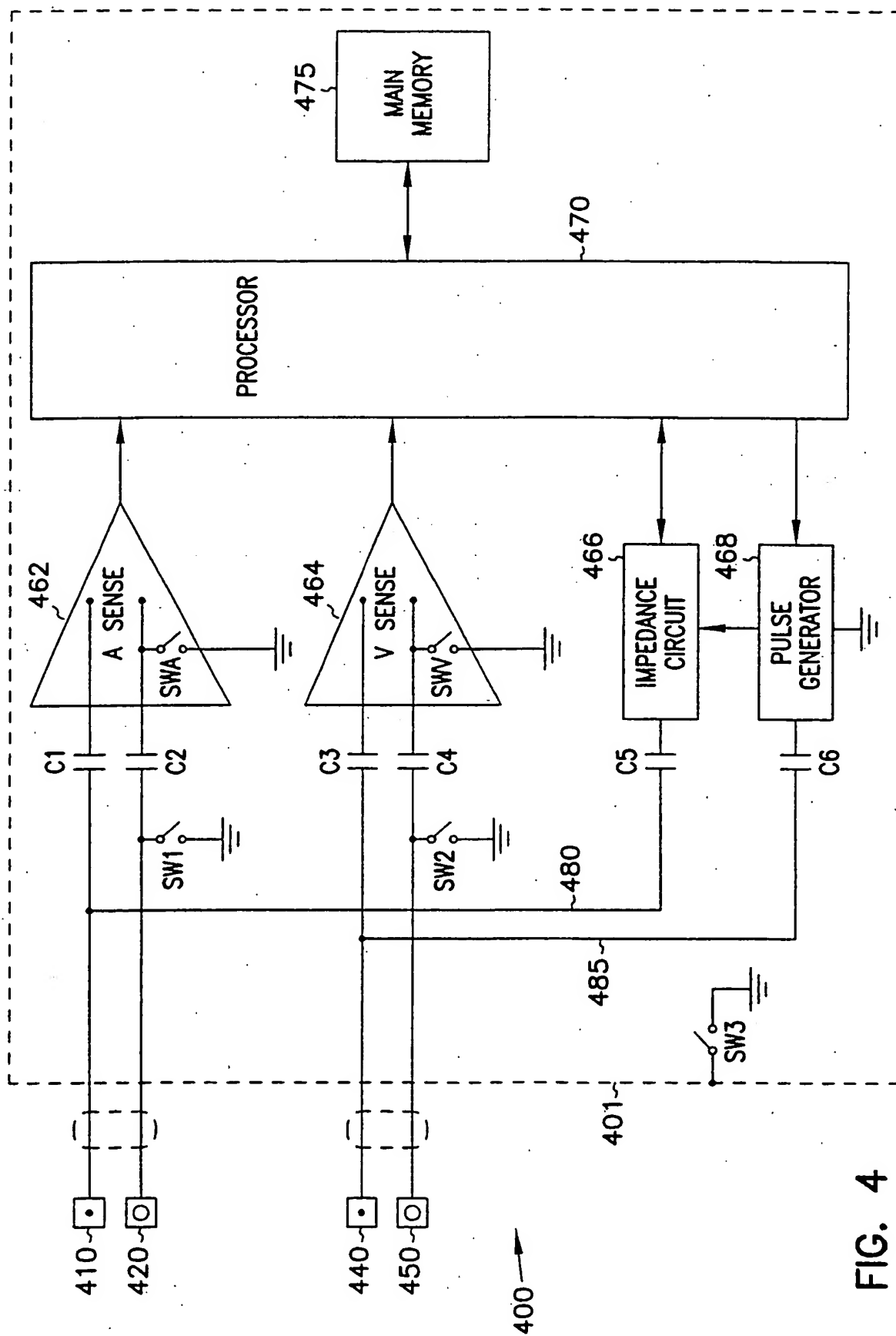


FIG. 4

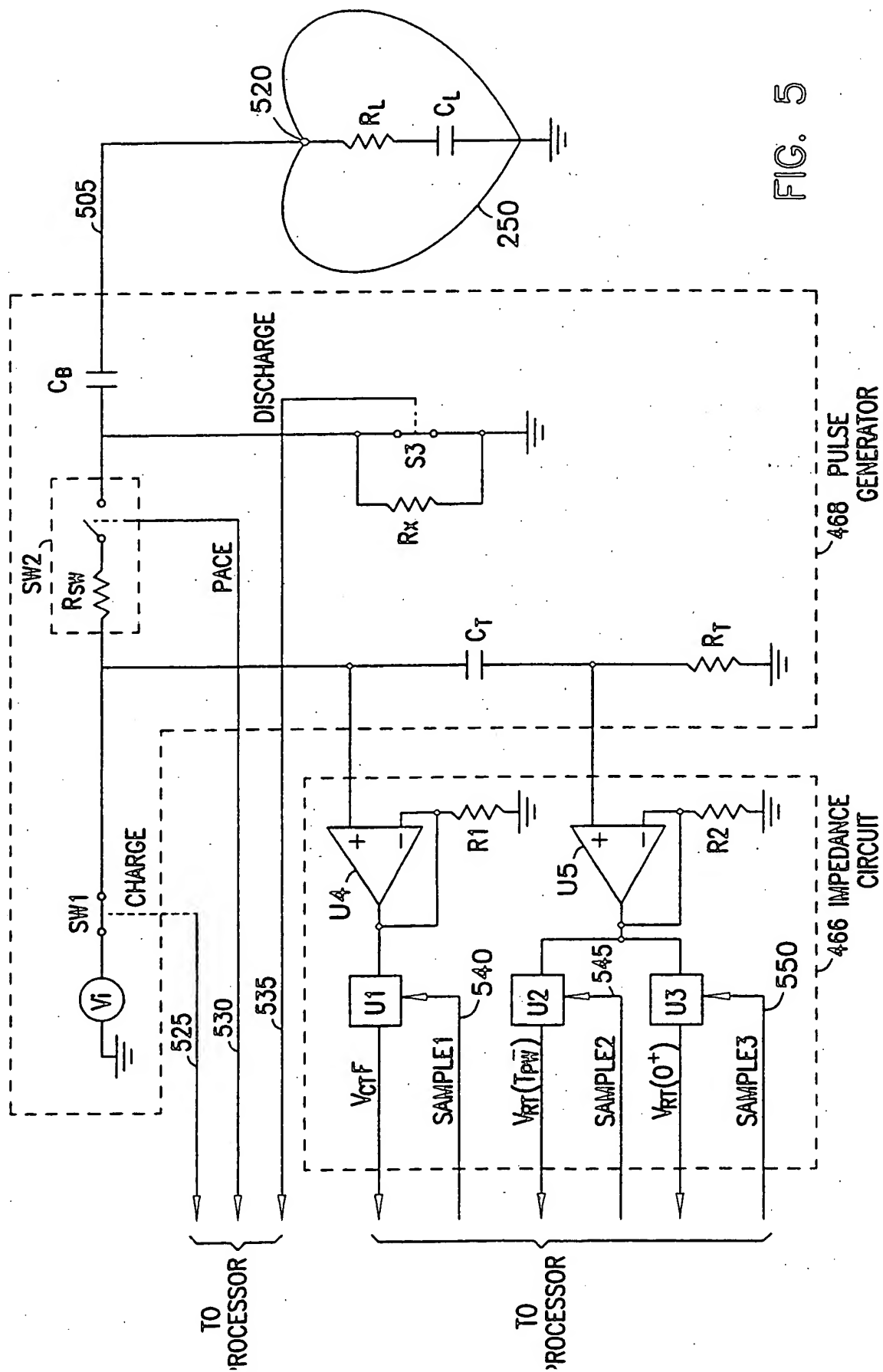


FIG. 5

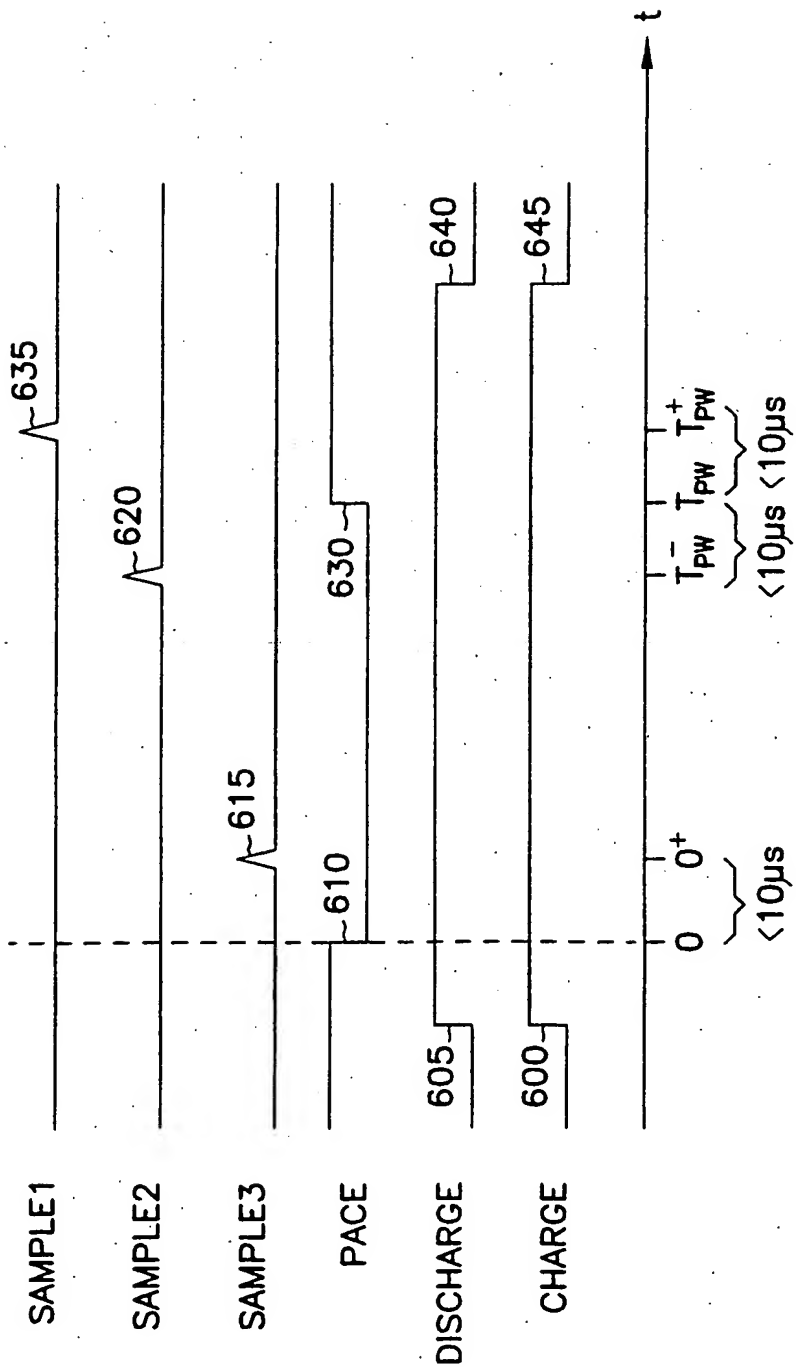


FIG. 6

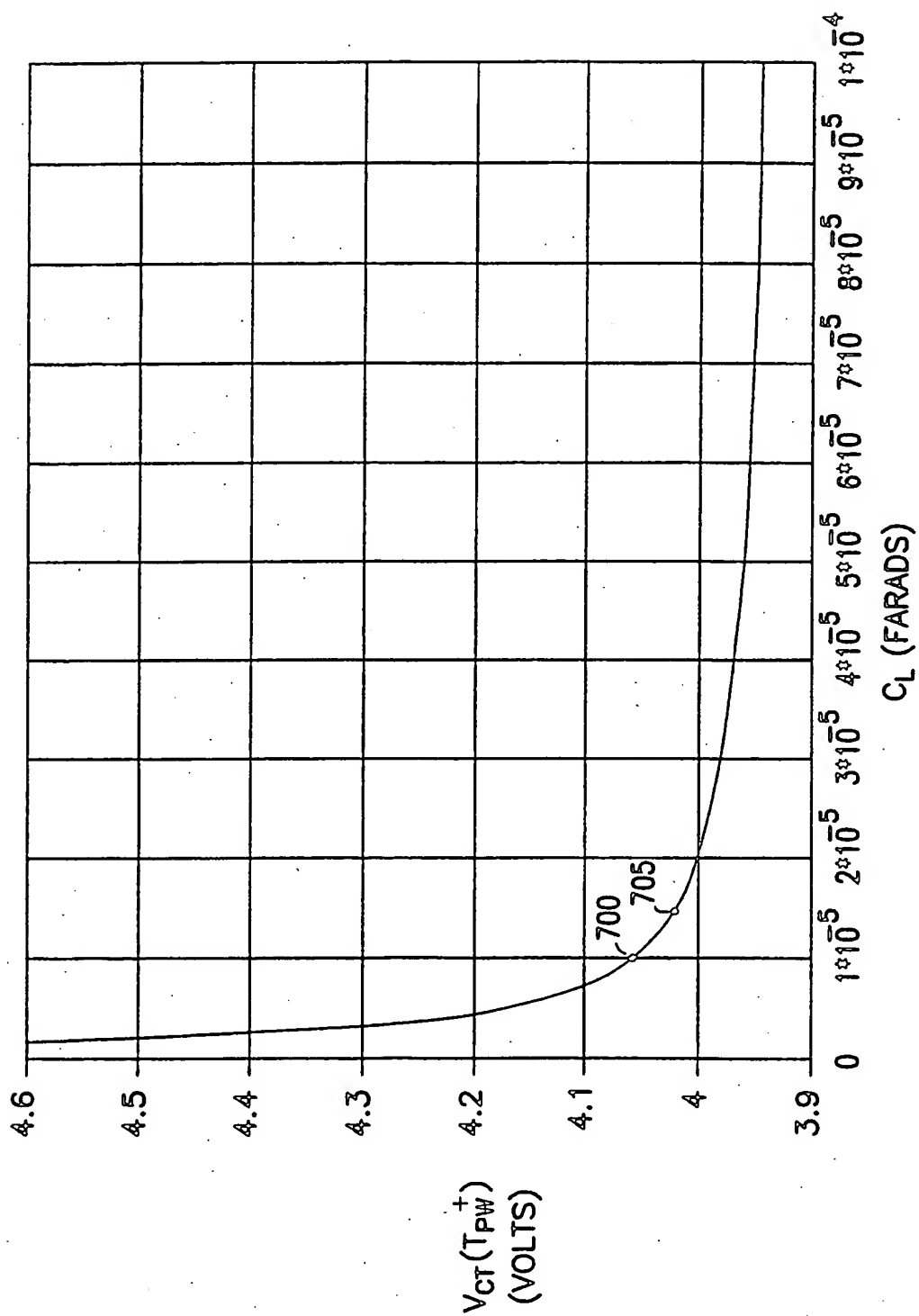
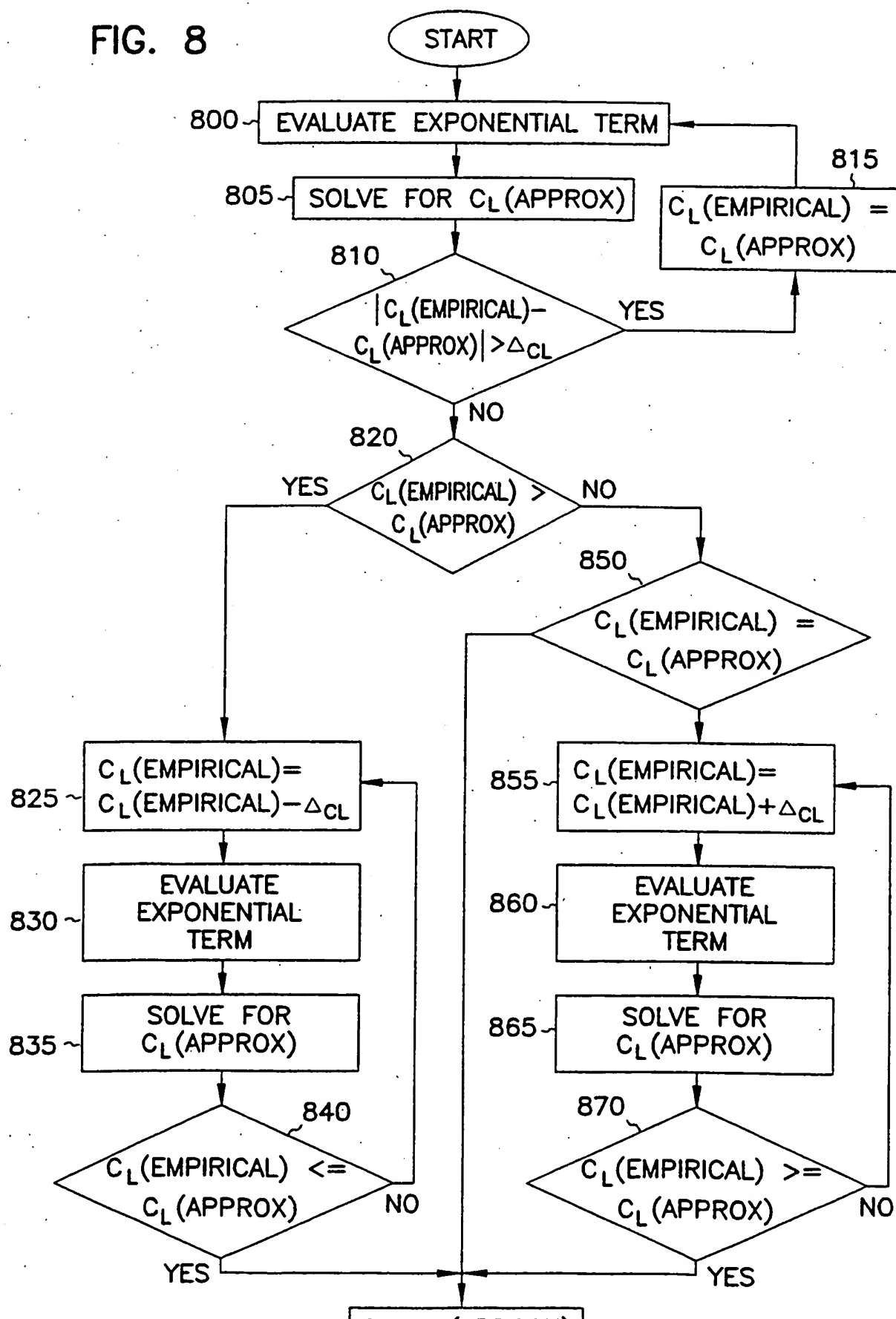


FIG. 7

FIG. 8



INTERNATIONAL SEARCH REPORT

International Application No

PCT/US 99/09877

A. CLASSIFICATION OF SUBJECT MATTER
IPC 6 A61N1/37

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)
IPC 6 A61N

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

C. DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| X | US 5 431 692 A (HANSEN DANIEL L ET AL) 11 July 1995 (1995-07-11) page 4, line 44 - line 65 column 6, line 36 - line 51 column 9, line 15 - column 10, line 5 column 11, line 40 - column 13, line 50 claim 3 | 16-20 |
| A | --- | 1-7, 21-24 |
| X | US 5 201 865 A (KUEHN KEVIN P) 13 April 1993 (1993-04-13) cited in the application abstract column 7, line 13 - column 9, line 20 column 10, line 3 - line 68 figures --- | 16 |
| | -/-- | |



Further documents are listed in the continuation of box C.



Patent family members are listed in annex.

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Date of the actual completion of the international search

24 August 1999

Date of mailing of the international search report

30/08/1999

Name and mailing address of the ISA

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NL-2000 HV Rijswijk

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INTERNATIONAL SEARCH REPORT

Inter. Patent Application No.

PCT/US 99/09877

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

| Category | Citation of document, with indication, where appropriate, of the relevant passages | Relevant to claim No. |
|----------|-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|-----------------------|
| A | <p>US 4 613 850 A (TIMMERMANN HARTWIG) 23 September 1986 (1986-09-23) abstract column 1, line 42 - line 50 column 2, line 22 - line 44 column 3, line 1 - line 66 figures</p> | 1,2,4,5, 16,21 |
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| A | <p>US 4 899 750 A (EKWALL CHRISTER) 13 February 1990 (1990-02-13) cited in the application the whole document</p> | 1,16,21 |

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/US 99/09877

| Patent document cited in search report | | Publication date | Patent family member(s) | Publication date |
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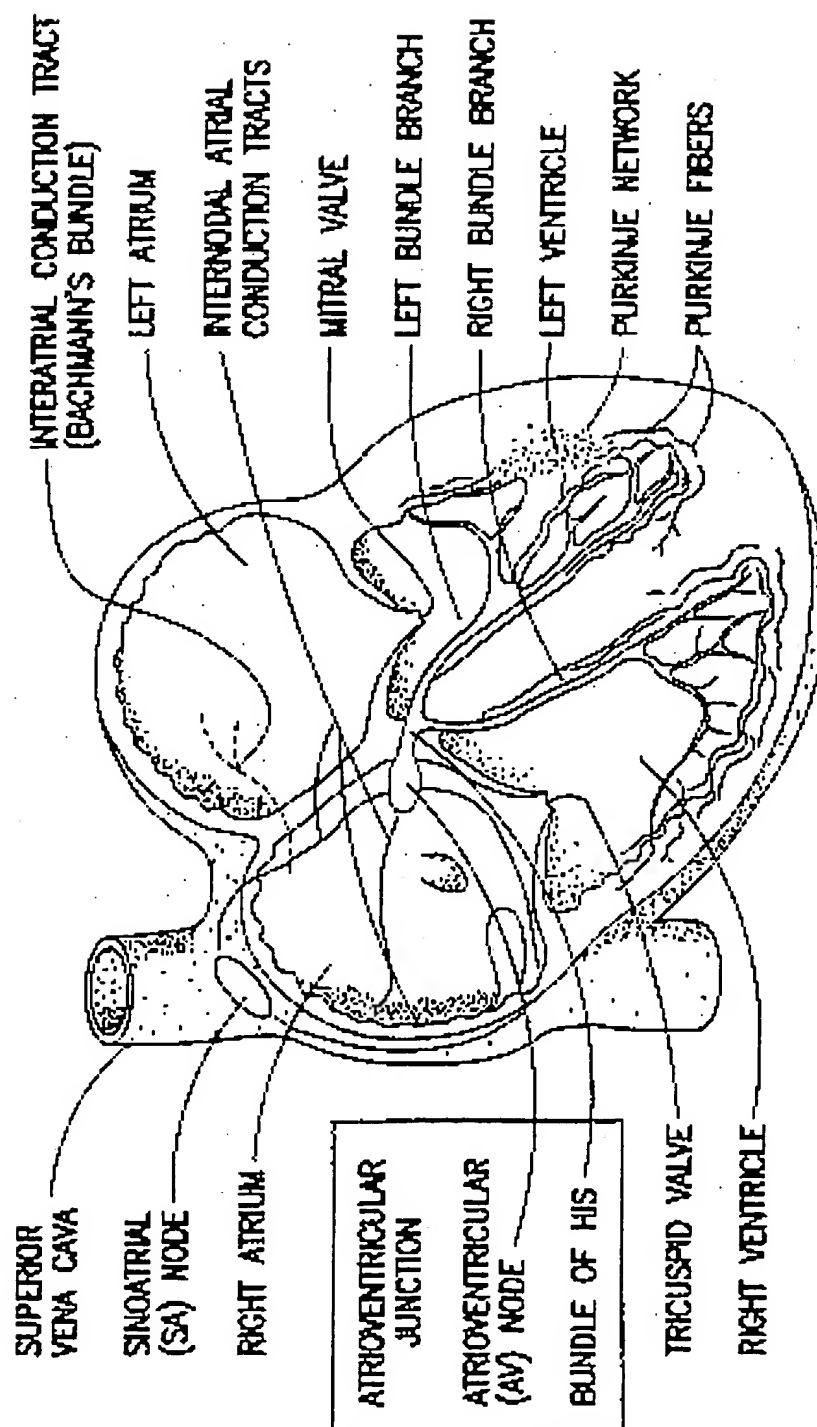


FIG. 1 (PRIOR ART)

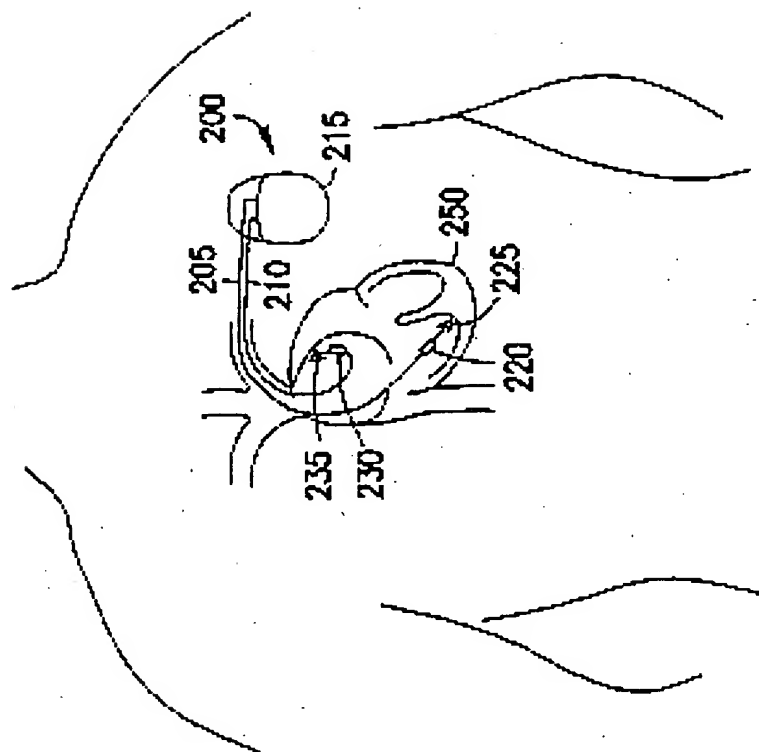


FIG. 2 (PRIOR ART)

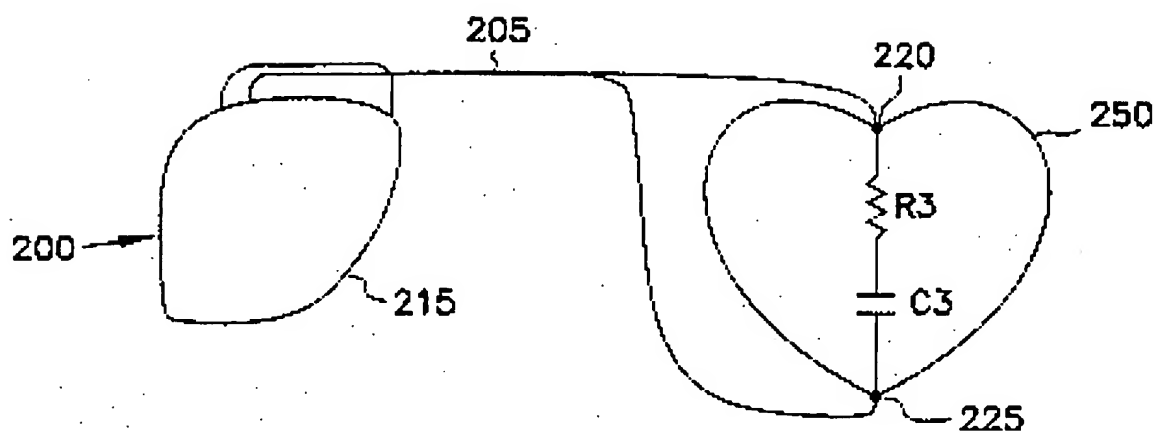


FIG. 3A (PRIOR ART)

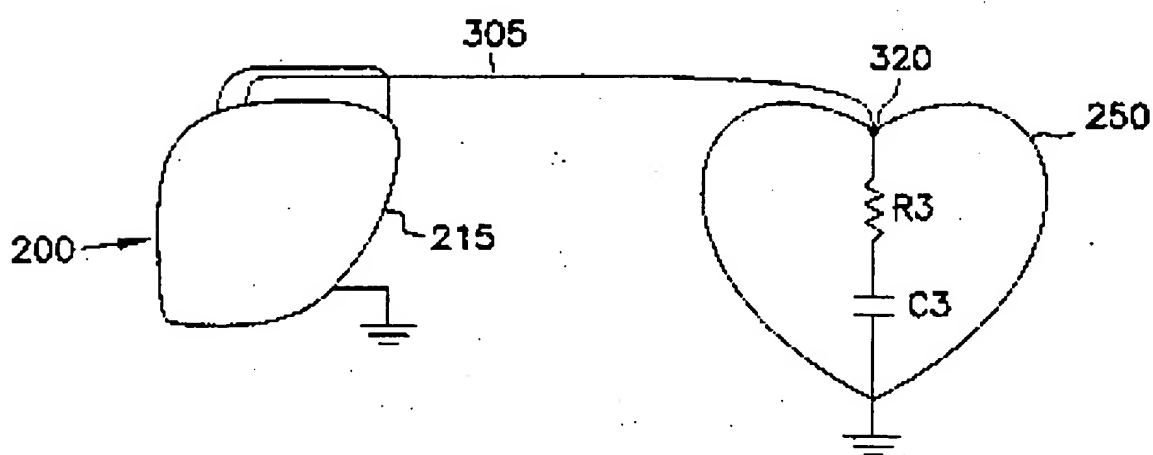


FIG. 3B (PRIOR ART)

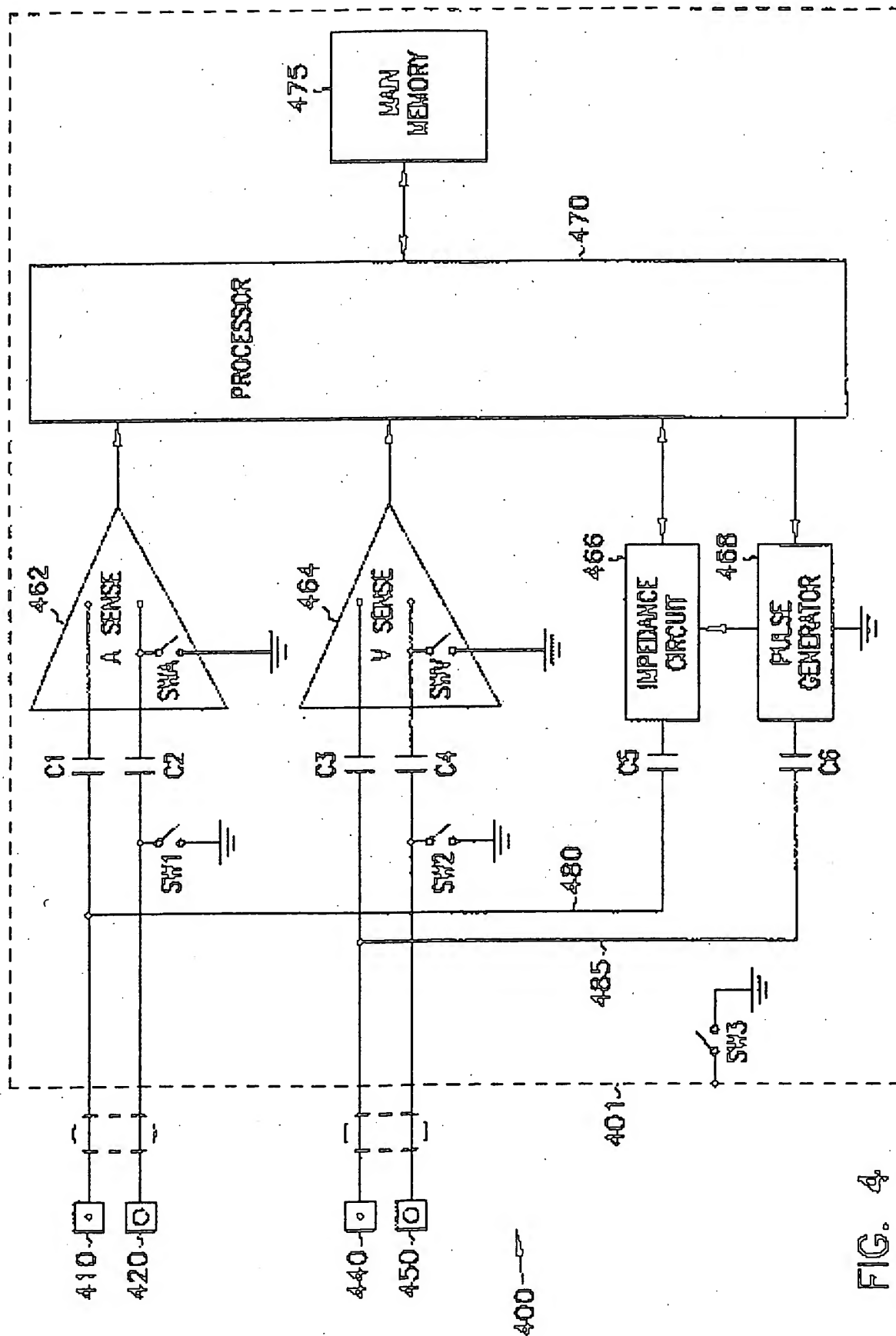
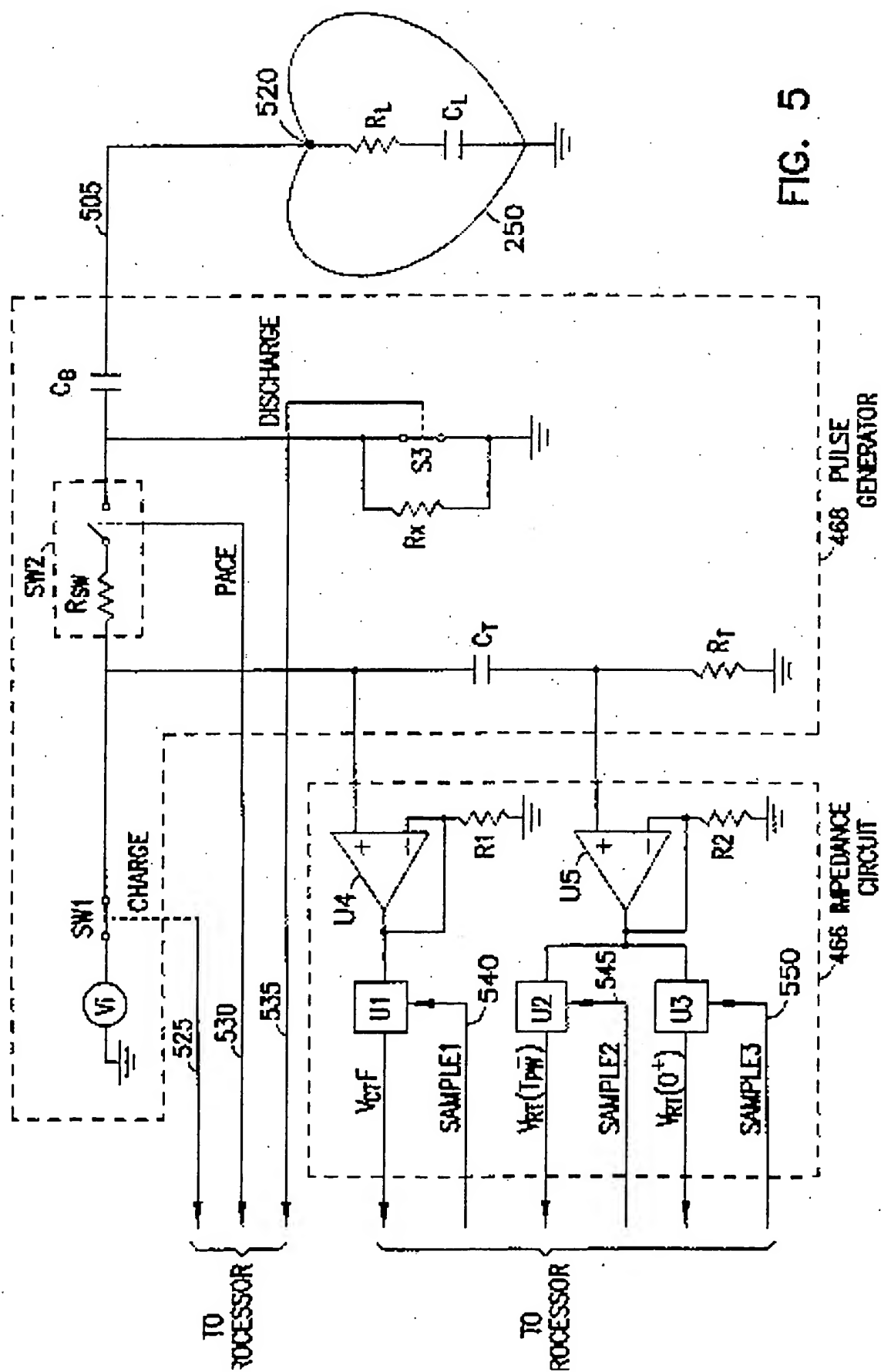


FIG. 4



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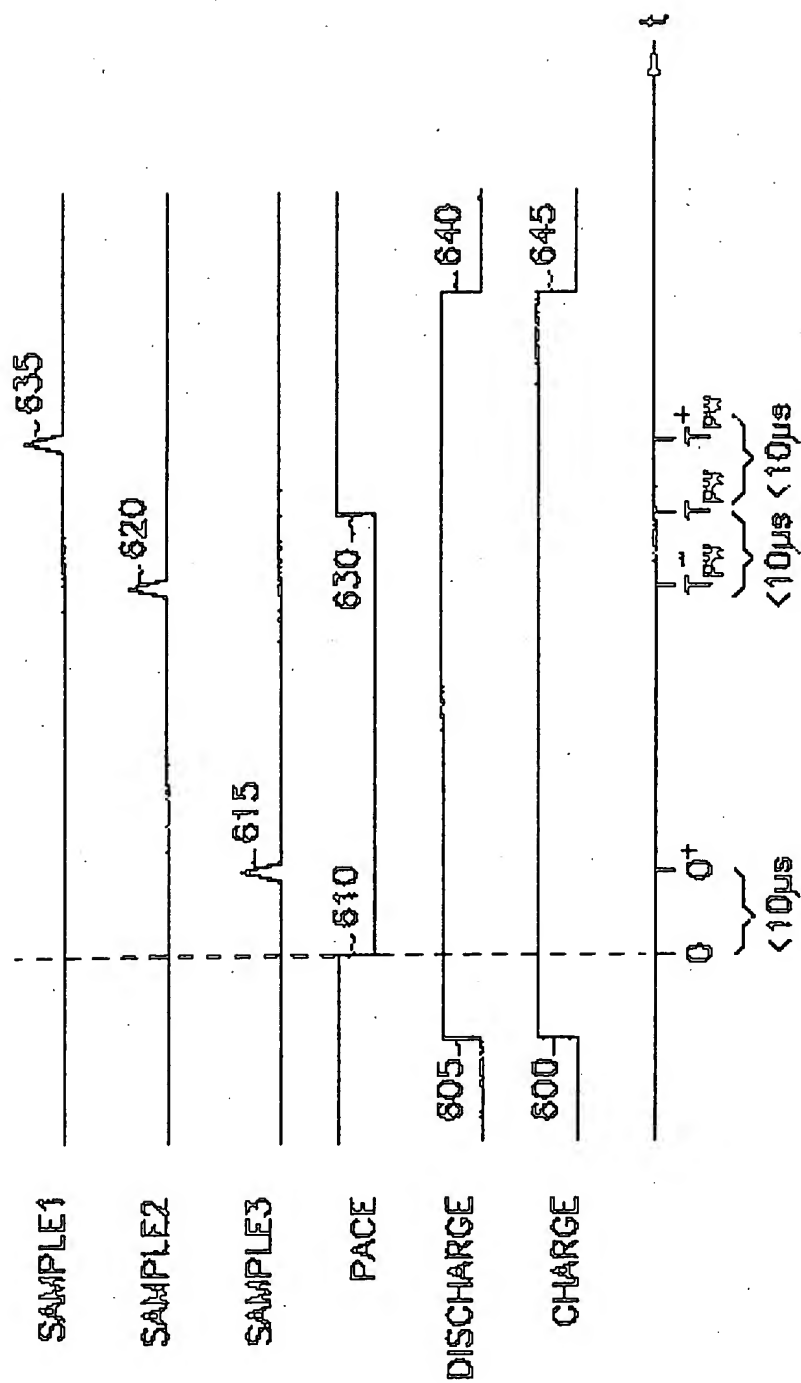


FIG. 6

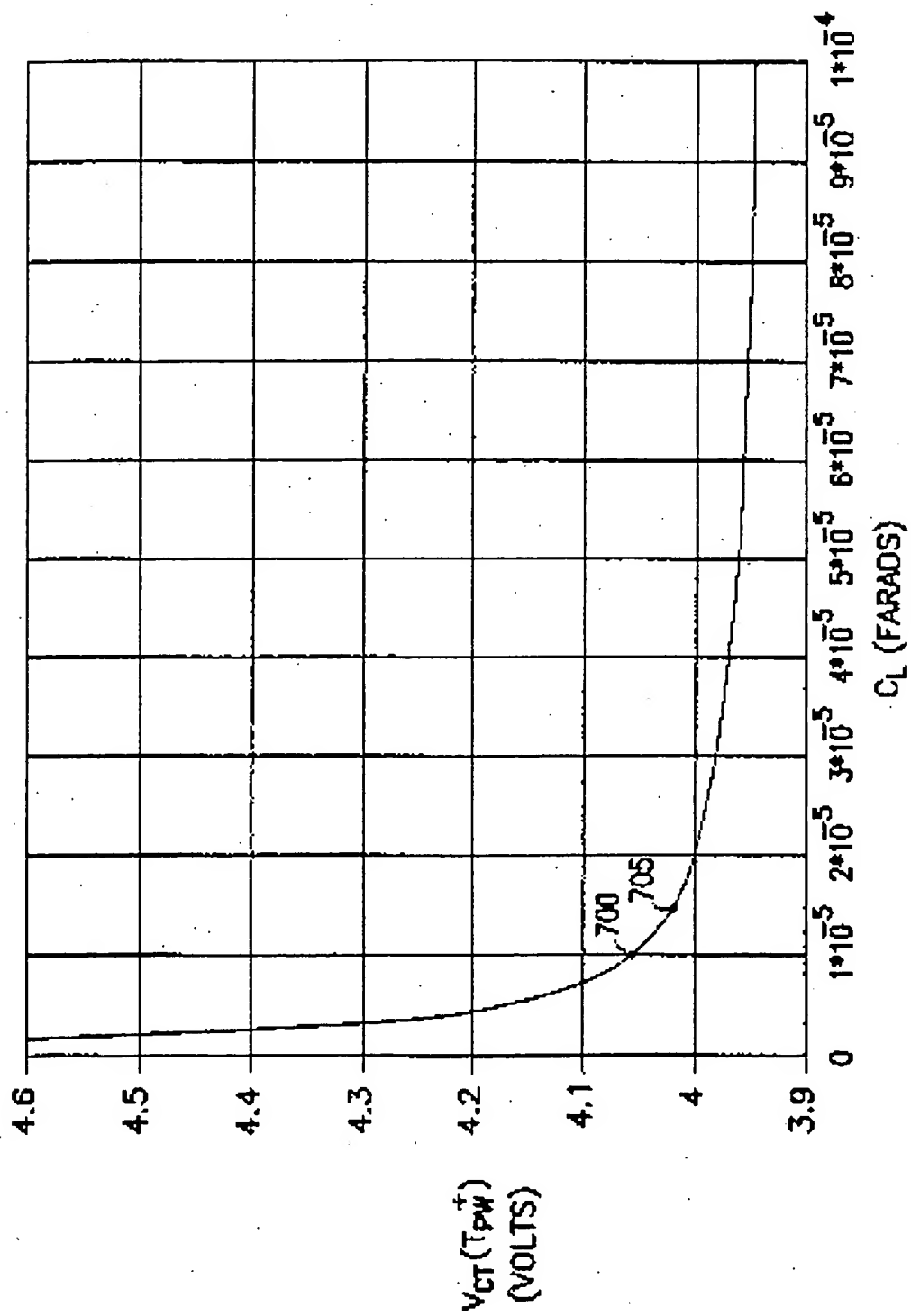


FIG. 7

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FIG. 8

